

Pharmacist's Manual

**An Information Outline of the
Controlled Substances Act of 1970**

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An Informational Outline of the Controlled Substances Act of 1970

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This manual has been prepared by the Drug Enforcement Administration's Office of Diversion Control to assist pharmacists in their understanding of the Federal Controlled Substances Act of 1970 and its implementing regulations as they pertain to pharmacy practice.

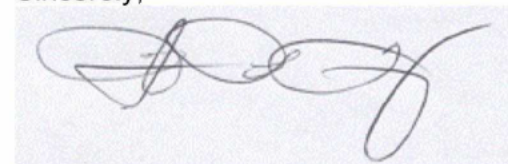
Message from the Administrator

Dear Pharmacist:

The Drug Enforcement Administration is pleased to provide you the eighth edition of the Pharmacist's Manual to assist you in understanding the provisions of the Controlled Substances Act (CSA) and its implementing regulations. This manual will answer questions you may encounter in the practice of pharmacy and provide guidance in complying with the CSA regulations. This edition has been updated to include information on the provisions of the Comprehensive Methamphetamine Control Act of 1996.

Your role in the proper dispensing of controlled substances is critical to the health of the patient and to safeguard society against drug abuse and diversion. Your adherence to the Controlled Substances Act, together with your voluntary compliance with its objectives, are a powerful resource for protecting the public health, assuring patient safety, and preventing the diversion of controlled substances and drug products containing listed chemicals.

Sincerely,



Karen P. Tandy
Administrator
Drug Enforcement Administration

Preface

The Drug Enforcement Administration (DEA) is responsible for advising DEA registrants how to comply with the federal law¹ regarding the handling of controlled substances and regulated chemicals. It is DEA's goal to maintain a positive working relationship with its pharmacy registrants. The DEA respects the professional integrity of pharmacists, the vast majority of whom comply with the law and its regulations in a responsible manner. The DEA understands that it can best serve the public interest by working with these pharmacists to develop cooperative programs for preventing diversion of legal pharmaceutical controlled substances into the illicit market.

DEA does not routinely inspect pharmacies for controlled substance violations, since this function is usually conducted by state authorities. However, DEA does investigate complaints of diversion from pharmacies and also investigates "doctor shoppers" and prescription forgers whose activities are confirmed through records located at the numerous pharmacies they patronize.

DEA would prefer to assist pharmacists to avoid and correct potential compliance violations, rather than seek administrative, civil or criminal action. However, when repeated efforts to remedy violations have not been successful, DEA is authorized under federal law to pursue legal action to correct these problems, prevent diversion related drug abuse, and protect the public safety. A lack of

¹ Controlled Substances Act of 1970 (Title 21, United States Code, Section 800 et. seq.) and its implementing regulations (Title 21, Code of Federal Regulations, Part 1300 to end).

compliance may result in a need for corrective action, such as administrative action (i.e., Letter of Admonition, an informal hearing or licensing action), or in extreme cases, civil or criminal action.

The DEA is greatly concerned about the diversion and abuse of controlled substances and drug products containing listed chemicals. Most drug diversion occurs at the retail level, where the pharmacist plays a critical role in supervising the proper control of prescription and over-the-counter drugs. Because the pharmacist dispenses controlled substances to the patient, he/she is in a key position to safeguard the health of the patient and prevent diversion. The pharmacist and the prescribing practitioner share responsibility for monitoring the therapeutic drug usage of patients, whose health depends on concerned and knowledgeable professionals.

Experience has shown that pharmacists who are familiar with the regulations are most successful in complying with the Controlled Substances Act. The CSA permits pharmacists to dispense controlled substances only when bona fide prescription orders are issued by practitioners authorized to prescribe controlled substances. Under the CSA, a valid prescription must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. While this responsibility rests on the prescriber, a corresponding responsibility rests upon the pharmacist who dispenses the prescription medication. A prescription which is not written for a legitimate medical purpose is not considered to be a valid prescription within the meaning of the law. The individual who knowingly dispenses such a purported prescription, as well as the individual issuing it, can be subject to criminal and /or civil penalties.

The pharmacist and the practitioner must be aware of the various techniques drug abusers and traffickers use to obtain controlled substances and drug products that contain

listed chemicals for illicit purposes. The primary method is a falsified prescription (see Appendix O, "**Pharmacist's Guide to Prescription Fraud**"). State and local law enforcement agencies, as well as pharmaceutical industry representatives, cite prescription fraud as a substantial part of the diversion problem. The DEA recognizes that attempts to obtain legitimately manufactured controlled substances by misrepresentation, such as forged prescriptions and stolen prescription blanks, are significant problems confronting practitioners, pharmacists, and local law enforcement agencies. "Doctor shoppers," who pose as patients to obtain controlled substances from multiple practitioners, are also a common source of diversion. Other methods for diverting controlled substances and drug products containing listed chemicals include theft from a pharmacy and diversion by pharmacy personnel.

New Chemical Control Requirements

In addition to the diversion of controlled substances, DEA is concerned with the diversion of certain chemicals used in the clandestine manufacture of controlled substances. Most pharmacies do not stock significant quantities of these chemicals. Chemicals such as ephedrine, pseudoephedrine, and phenylpropanolamine (PPA)² which are contained in prescription and over-the-counter preparations are sold at retail stores. Drug products containing these chemicals are commonly used to illegally manufacture amphetamine and methamphetamine. Quantities of these drug products may be sought from retail outlets for use in clandestine manufacturing operations.

² Due to concerns regarding harmful side effects of phenylpropanolamine (PPA), the Food and Drug Administration initiated action in November 2000 to remove PPA from the market. These changes in the status of PPA are not yet reflected in the regulation or this manual

Consequently, these chemicals are subject to certain registration, recordkeeping and reporting requirements. As a rule, pharmacies are retail outlets and therefore are not required to have a chemical registration. However, because diversion of drug products containing these chemicals can occur at the retail level, appropriate safeguards are necessary to prevent diversion. Close cooperation between the pharmacy profession and law enforcement will help ensure that the chemicals used in the production of illicit controlled substances remain in legitimate channels. (For more information see Chemical Requirements as well as Appendices A, B and C).

If you need additional clarification or assistance concerning the CSA regulations or wish to comment on the material in this manual, please contact your local DEA Diversion Field Office (see Appendix T).

DEA's Internet Website:

www.DEA.gov

You can access the diversion control program website from DEA's website by hyperlink.

DEA Diversion Control Program's Internet Website:

www.DEAdiversion.usdoj.gov

This site includes Diversion Control Program newsletters, Federal Register Notices, DEA manuals **and publications; progress reports regarding DEA's electronic commerce initiatives, listings of DEA Diversion and Registration Field Offices, conferences, and items on Diversion's major program areas (e.g., registration, regulated chemicals, scheduling issues, and ARCOS).**

The complete text of the Pharmacist's Manual can be found on the Diversion Control Program website under

Publications. The manual will be updated periodically so that current information is available on the DEA website. Therefore the manual can be downloaded and reproduced at your convenience without having to request a print copy by mail from DEA. The manuals for physicians, mid-level practitioners, researchers and chemical handlers will also be available on this website.

GPO Federal Register Internet Website:

<http://www.access.gpo.gov/nara/cfr/index.html>

DEA Regulations and Notices in the Federal Register

DEA regulations and notices published in the Federal Register are available online through the U.S. Government Printing Office (GPO) Internet website. The current Code of Federal Regulations³ as well as proposed and finalized amendments to the CFR concerning controlled substances and regulated chemicals, can be found at this website.

In addition, a hard copy of the CFR may also be obtained through the GPO in your local area, or by writing to the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

³ To find the Code of Federal Regulations pertaining to controlled substances and regulated chemicals use 21 CFR, Part 1300 to end.

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Application of State and Federal Laws

Nothing in this manual shall be construed as authorizing or permitting any person to do any act which is not authorized or permitted under federal or state laws. In addition, none of the policy statements and information in this manual may be construed as authorizing or permitting any person to do any act which is not authorized. ***Use of a DEA controlled substance registration for activities not authorized under state law is a violation of both federal and state law.***

Furthermore, this manual does not authorize a pharmacist to refuse to meet any requirements in the most recent publication of Title 21, Chapter II of the Code of Federal Regulations (21 CFR, Part 1300 to end). The CFR is the primary source for the Pharmacist's Manual. Printed copies of the complete regulations implementing the Controlled Substances Act of 1970 may be obtained from:

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402

Both the Code of Federal Regulations and the Federal Register (which includes proposed and finalized regulations implementing the CSA) are available on the Internet through the U.S. Government Printing Office (GPO) website. This site, which provides information by section, citation and key words, can be accessed at:

<http://www.access.gpo.gov/nara/cfr/index.html>

DEA registration grants pharmacies authority to dispense controlled substances. However, DEA registered pharmacies may only engage in those activities which are authorized under state law in the jurisdiction where the pharmacy is located. In many cases state law is more stringent than federal law, and must be complied with in addition to federal law. Pharmacists should make sure they understand their state and DEA controlled substance regulations.

Drug Enforcement Administration

The Drug Enforcement Administration (DEA) is the primary agency within the Federal Government responsible for the enforcement of the Controlled Substances Act (CSA). In cooperation with state authorities and other federal agencies, DEA is tasked with preventing the diversion of controlled substances for illicit purposes. In carrying out its mission, DEA complies with international treaty obligations, works closely with foreign as well as domestic state and local governments, private industry, and other organizations concerned with drug abuse and diversion.

The CSA, which became effective May 1, 1971, consolidates into one piece of legislation many diverse laws passed by Congress since the Harrison Narcotics Act of 1914, the first comprehensive federal legislation to control addicting drugs. Subsequent amendments to the CSA include the 1984 Diversion Control Amendments, the Controlled Substance Registrant Protection Act of 1984, the Narcotic Addict Treatment Act of 1984, the Chemical Diversion and Trafficking Act of 1988, the Domestic Chemical Diversion Control Act of 1993, and the Comprehensive Methamphetamine Control Act of 1996.

The provisions of the CSA are designed to improve the administration and regulation of the manufacture, import/export, distribution and dispensing of controlled substances by providing a "closed system" for distribution. Under this closed system, a controlled substance can be traced from the time it is manufactured to the time it is dispensed to the ultimate user. This system has proven effective in reducing the diversion of these substances from legitimate channels to the illicit market.

Schedules of Controlled Substances

The controlled substances and their derivatives listed under the CSA can be found in the Code of Federal Regulations, Title 21 under "Part 1308--Schedules of Controlled Substances."

The drugs and drug products under the jurisdiction of the CSA are divided into five schedules. **Controlled substances in Schedules II-V have an accepted medical use in the United States, and Schedule I substances do not.** The characteristics and some examples of the drugs in each schedule are outlined below.

Schedule I Substances

The substances in this schedule have a **high abuse potential** and **no accepted medical use in the United States**. This is the only schedule that includes drugs that are not available for prescribing, dispensing or administering. DEA does allow for research involving Schedule I substances. This requires a separate registration as a researcher.

Examples of substances classified as Schedule I narcotics include heroin, certain clandestinely made fentanyl analogs, and propiram. Some hallucinogenic substances found in Schedule I include heroin, LSD, marijuana, and MDMA (Ecstasy).

Other examples of Schedule I substances are the depressants methaqualone and gamma hydroxybutyric acid (GHB) and the stimulant methcathinone.

Schedule II Substances

Substances in Schedule II have a high abuse potential with severe psychological or physical dependence liability, have an accepted medical use in the United States, and are available for practitioners to prescribe, dispense and administer.

Some examples of single entity Schedule II narcotics include morphine, codeine, hydrocodone, and opium. Other

Schedule II narcotic substances and their common name brand products include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (Percodan®) and fentanyl (Sublimaze®).

Some examples of Schedule II stimulants include amphetamine (Dexedrine®), Adderall®, methamphetamine (Desoxyn®) and methylphenidate (Ritalin®).

Other Schedule II substances include cocaine, amobarbital, glutethimide, pentobarbital and secobarbital.

Schedule III Substances

The substances in this schedule have an abuse potential which is less than those in Schedule II, but more than Schedule IV substances.

Some examples of Schedule III narcotics include products containing less than 15 milligrams of hydrocodone per dosage unit (i.e., Vicodin®, Lorcet®, Tussionex®, and products containing not more than 90 milligrams of codeine per dosage unit (i.e., codeine with acetaminophen, aspirin or ibuprofen).

Other Schedule III substances include anabolic steroids benzphetamine (Didrex®) phendimetrazine, and any compound, mixture, preparation or suppository dosage form containing amobarbital, secobarbital, pentobarbital, dronabinol (Marinol®) or ketamine and buprenorphine (Buprenex®).

Schedule IV Substances

The substances in this schedule have an abuse potential less than those listed in Schedule III and more than substances in Schedule V.

Some examples of Schedule IV narcotics include propoxyphene (Darvon®), butorphanol (Stadol®), and pentazocine (Talwin-NX®).

The following benzodiazepine substances are also found in Schedule IV. They include alprazolam (Xanax®), clonazepam

(Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), flurazepam (Dalmane®), halazepam (Paxipam®), lorazepam (Ativan®), midazolam (Versed®), orazepam (Serax®), prazepam (Verstran®), temazepam (Restoril®), triazolam (Halcion®), and quazepam (Doral®).

Other Schedule IV substances include barbitol, phenobarbital, chloral hydrate, ethchlorvynol (Placidyl®), chlordiazepoxide (Librium®), ethinamate, meprobamate, paraldehyde, methohexital, phentermine, diethylpropion, pemoline (Cylert®), mazindol (Sanorex®), and sibutramine (Meridia®).

Schedule V Substances

The substances in this schedule have an abuse potential less than those listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotic and stimulant drugs generally for antitussive, antidiarrheal and analgesic purposes. Some examples are cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®), Phenergan with codeine®).

Registration Requirements

Every pharmacy which dispenses any controlled substance must be registered with the DEA. Since DEA does not register pharmacists, they must obtain their license to practice pharmacy from their state regulatory authority. To obtain a DEA registration, a pharmacy can request a DEA Form-224 (Application for New Registration, see Appendix E) from any DEA Registration Field Office (see Appendix T) or from the DEA Headquarters Registration Unit in Washington, D.C. at 1-800-882-9539 (Registration Call Center). DEA Form 224 is also available online and in PDF format at www.DEAdiversion.usdoj.gov. The DEA Form 224 is fully interactive, including the acceptance of electronic credit card payments.

The completed DEA Form-224 must be submitted to:

**Drug Enforcement Administration
Registration Unit
Central Station
P.O. Box 28083
Washington, D.C. 20038-8083**

Pharmacy registrations must be renewed every three years. The cost of the registration is annotated on the application form. The certificate of registration must be maintained at the registered location and kept available for official inspection. If a person owns and operates more than one pharmacy, each place of business must be registered.

Every pharmacy currently registered with DEA will receive a renewal application approximately 45 days before the registration expiration date. The renewal application will be sent to the address listed on the current registration certificate. If the renewal form is not received within 30 days before the expiration date of the current registration, the pharmacy should contact the DEA registration unit for their state (see Appendix T), and request a renewal registration form.

Chemical Registration Requirements

Under DEA's Chemical Control regulations there is an exemption from the registration requirement for a retail distributor. A retail distributor is defined as a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor of legal drug products containing listed chemicals pseudoephedrine, phenylpropanolamine (PPA), combination ephedrine and single-entity ephedrine are limited almost exclusively to sales for personal use, both in number and volume of sales, either directly to walk-in customers or in face to face transactions. Personal use means the distribution of below "threshold quantities"⁴ in a single transaction to an individual for legitimate medical use.

⁴ The quantity of a particular chemical, above which recordkeeping and other control provisions of the CSA apply. See Appendix A "Number of Tablets that Equal a Threshold (Regulated) Transaction for Dosage Units of Marketed Products"

Federal law requires any person who is engaged in the wholesale distribution of drug products containing List I chemicals to obtain a registration as a chemical distributor. A distributor who does not meet all the requirements for a retail distributor is a ***wholesale distributor***.

Retail pharmacies that are registered to handle controlled substances need not obtain a separate DEA chemical registration for retail distribution of the drug products containing pseudoephedrine, phenylpropanolamine (PPA), combination ephedrine and single-entity ephedrine which are regulated as List I chemicals. If a pharmacy desires to engage in the wholesale distribution of bulk quantities of these drug products, the pharmacy will have to register with DEA as a Chemical Distributor because these activities fall outside of the definition of retail distributor. Therefore, the pharmacy would be subject to the registration requirements that apply to wholesale distributors.

To obtain a DEA Chemical Distributor registration, a pharmacy can request DEA Form-510 (Application for Registration, see Appendix M) from any DEA Registration Field Office (see Appendix T)

For additional information see Chemical Requirements: Comprehensive Methamphetamine Control Act of 1996.

New Pharmacy Registration

Pharmacies seeking to become registered for the first time must request a DEA Form-224 (Application for New Registration, see Appendix E) from any DEA Registration Field Office or the DEA Registration Unit in Washington, D.C. at the address listed under Registration Requirements.

Any pharmacy engaged in co-op buying of controlled substances must also register as a distributor with the DEA. To obtain this registration, a pharmacy must meet distributor (wholesaler) security and recordkeeping requirements.

An affidavit system for expediting pharmacy applications may be used to obtain a DEA registration number for a new pharmacy or for transferring ownership of an existing pharmacy. If the pharmacy has been registered by the state licensing agency, the applicant may include an affidavit (see Appendix P) to verify the existence of the state license with their application (21 CFR 1301.17).

Change of Business Address

Any time a pharmacy moves to a new physical location or the postal address changes at the same location, a new DEA certificate reflecting the new address must be obtained. It is the pharmacy's responsibility to notify DEA about a change of address before the effective date of the move. A written request for modification of registration should be sent to the DEA Registration Field Office responsible for their state (see Appendix T). If the modification is approved, DEA will issue a new certificate of registration and, if requested, new Schedule II order forms (DEA Form-222, Official Order Form). A Renewal Application for Registration (DEA Form-224a) will only be sent to the registered address on file with DEA. It cannot be forwarded.

Affidavit for Renewal of Retail Chain Pharmacy Registration

Corporations that own or operate a chain of pharmacies may submit a single DEA Form-224b (Retail Pharmacy Registration Affidavit for Chain Renewal, see Appendix G) that covers all the chain's pharmacy registrants. This affidavit along with a list of the corporation's registrations is provided in lieu of a separate DEA application for each pharmacy registration. No registration may be issued unless the completed affidavit is received by DEA. **The corporation should retain a copy of this affidavit with their readily retrievable records for the duration of the registration covered by the affidavit.** The corporation

must answer the questions listed on the affidavit as they pertain to each registrant.

The original affidavit along with the registration fee and the list of registrations should be mailed to:

Registration Chain Renewal
United States Department of Justice
Drug Enforcement Administration
Central Station
P.O. Box 28083
Washington, D.C. 20038-808

Denial, Revocation or Suspension of Registration

Diversion of legitimately manufactured controlled substances is a serious problem in the United States. Registrants serve as the nation's primary guardians for preventing diversion and controlling legitimate access to these drugs. The CSA provides the Federal Government with additional legal resources for taking action against those registrants who contribute to the diversion problem. The U.S. Attorney General has the authority to suspend or revoke a DEA registration upon a finding that the registrant has:

1. Materially falsified any application filed.
2. Been convicted of a felony relating to a controlled substance or a List I Chemical.
3. Had his/her state license or registration suspended, revoked or denied.
4. Committed an act which would render his registration inconsistent with the public interest.
5. Been excluded from participation in a Medicaid or Medicare program.

Denial of Registration in the Public Interest

The CSA gives the U.S. Attorney General authority to deny any application for DEA registration or renewal if it is determined that issuing a controlled substance registration would be inconsistent with the public interest. In determining the public interest, the CSA states the following factors will be considered:

1. The recommendation of the appropriate state licensing board or professional disciplinary authority.
2. The applicant's experience in dispensing or conducting research with respect to controlled substances.
3. The applicant's conviction record under federal or state laws relating to the manufacture, distribution or dispensing of controlled substances.
4. Compliance with applicable state, federal or local laws relating to controlled substances.
5. Such other conduct which may threaten the public health and safety.

Termination of Registration

Any registrant who discontinues his/her business or transfers it to another person must notify the nearest DEA Registration Field Office (see Appendix T) in writing before terminating the pharmacy's registration. Along with the notification of termination of registration, the pharmacist should send the DEA Certificate of Registration and any unused Official Order Forms (DEA Form-222). The pharmacist should write or stamp the word "VOID" across the face of each Official Order Form before returning them to DEA. The notification to DEA should also indicate where the controlled substance inventories and records will be kept and how the controlled substances were transferred or destroyed. Records involving controlled substances must be kept

available for two years for inspection and copying by the DEA. This requirement applies even though the business has been discontinued.

Transfer of Business

A registrant transferring a pharmacy business to another registrant shall notify the nearest DEA Registration Field Office at least 14 days before the date of the proposed transfer and provide the following information:

1. The name, address, registration number of the registrant discontinuing business;
2. The name, address, registration number of the registrant acquiring the pharmacy;
3. Whether the business activities will be continued at the location registered by the current business owner or moved to another location. If the latter, give the address of the new location.
4. The date on which the controlled substances will be transferred to the person acquiring the pharmacy (see **Transfer of Controlled Substances** on page 10).

On the day the controlled substances are transferred, a complete controlled substances inventory must be taken and a copy of the inventory must be included in the records of both the person transferring the business and the person acquiring the business. Procedures for transferring the ownership of a pharmacy and a model format for an affidavit to expedite the process are outlined in Appendix Q.

If the registrant acquiring the pharmacy owns at least one other pharmacy licensed in the same state as the pharmacy being transferred, the registrant may apply for a new DEA registration prior to the date of transfer. DEA will issue a registration which will authorize the registrant to obtain controlled substances at the time of transfer. But the registrant may not dispense controlled substances until the pharmacy has been issued a valid state pharmacy license.

A DEA registration application for transferring ownership of an existing pharmacy can be expedited if the applicant includes an affidavit (see Appendix Q) verifying that the pharmacy has been registered by the state licensing agency. The affidavit verifying the existence of the state license should be attached to the initial application for registration.

Disposal of Controlled Substances

The pharmacy may hire an outside firm to inventory, package and arrange for the transfer of its controlled substances to another pharmacy, supplier or manufacturer. The pharmacy is responsible for the actual transfer of the controlled substances and for the accuracy of the inventory and records. The pharmacy may also transfer the drugs to a distributor registered with DEA to destroy drugs (reverse distributor). The pharmacy may not turn over any controlled substances to a distributor **unless the reverse distributor is registered to destroy controlled substances. The pharmacy is responsible for verifying that the reverse distributor is registered with DEA.**

The records involving the transfer or destruction of controlled substances must be kept readily available for two years for inspection and copying by the DEA. The two primary methods for disposing of controlled substances are transfer to another registrant or destruction as explained in the following section.

Transfer of Controlled Substances

If a pharmacy goes out of business or is acquired by a new pharmacy, it may transfer the controlled substances to another pharmacy, supplier, manufacturer or distributor registered to dispose of controlled substances.

To transfer **Schedule II substances**, the receiving registrant must issue an **Official Order Form** (DEA Form-222, U.S. Official Order Forms - Schedules I & II) to the registrant transferring the drugs.

The transfer of **Schedule III-V controlled substances** must be documented in writing to show the drug name, dosage form, strength, quantity and date transferred. The document must include the names, addresses and DEA registration numbers of the parties involved in the transfer of the controlled substances.

To Another Pharmacy⁵

On the day the controlled substances are transferred, a complete inventory must be taken which documents the drug name, dosage form, strength, quantity, and date transferred. In addition DEA Form-222 (Official Order Form) must be prepared to document the transfer of Schedule II controlled substances. This inventory will serve as the final inventory for the registrant going out of business and transferring the controlled substances. It will also serve as the initial inventory for the registrant acquiring the controlled substances. A copy of the inventory must be included in the records of each person. It is not necessary to send a copy of the inventory to the DEA. The person acquiring the controlled substances must maintain all records involved in the transfer of the controlled substances for two years.

To Another Supplier or Manufacturer

Any pharmacy may transfer controlled substances to a supplier or a manufacturer. The pharmacist must maintain a written record showing:

1. The date of the transaction.
2. The name, strength, form and quantity of the controlled substance.
3. The supplier's or manufacturer's name, address, and, if known, registration number.

⁵ See also the section entitled "Controlled Substance Distribution by Pharmacy".

4. The DEA Form-222 will be the official record for the transfer of Schedule II substances.

To a Reverse Distributor Registered to Dispose of Controlled Substances

Any pharmacy may forward controlled substances to DEA-registered reverse distributors who handle the disposal of drugs. For further instructions see, **Disposal of Controlled Substances**.

Destruction of Controlled Substances

DEA recommends that any pharmacy seeking to dispose of controlled substances first contact the nearest DEA Diversion Field Office (see Appendix T) for disposal instructions. In no case should drugs be forwarded to the DEA unless the registrant has received prior approval from the DEA. The DEA procedures established for the destruction of controlled substances shall not be construed as altering in any way the state laws or regulations for the disposal of controlled substances. Requests from registrants seeking authorization to destroy controlled substances without DEA presence, or requests from non-registrants desiring to dispose of controlled substances will be handled as follows:

Once-a-Year DEA Authorization for Destruction

Once each calendar year retail pharmacies may request DEA authorization to destroy damaged, outdated or otherwise unwanted controlled substances. The pharmacy must complete DEA Form-41 (Registrants Inventory of Drugs Surrendered, see Appendix I), listing all drugs to be destroyed. In addition, the pharmacy must prepare a letter requesting permission to destroy the controlled substances, proposing a date and method of destruction, and listing the names of at least two people who will

witness the destruction. The witnesses should be either a licensed physician, pharmacist, mid-level practitioner, nurse, or a state or local law enforcement officer. Both documents must be received by the nearest DEA Diversion Field Office at least two weeks prior to the proposed destruction date. After reviewing all available information, the DEA office will then notify the registrant in writing of its decision. Once the controlled substances have been destroyed, signed copies of the DEA Form-41 must be forwarded to DEA. The pharmacist should contact local environmental authorities prior to implementing the proposed method of destruction to ascertain that hazards are not associated with the destruction.

Exception to DEA Authorization for Destruction

Prior DEA authorization to destroy controlled substances is not necessary when an authorized member of a state law enforcement authority or regulatory agency witnesses the destruction. Copies of a DEA Form-41 or state controlled substance destruction form must be forwarded to the local DEA Diversion Office after the destruction.

Reverse Distributors Authorized to Destroy Controlled Substances

A pharmacy may at any time forward controlled substances to DEA registered reverse distributors who handle the disposal of drugs. The pharmacist may contact their local DEA Diversion Field Office for an updated list of those reverse distributors in their area. When a pharmacy transfers **Schedule II substances** to a reverse distributor for destruction, the distributor must issue an Official Order Form (DEA Form-222) to the pharmacy. When **Schedule III-V controlled substances** are transferred to a reverse distributor for destruction, the pharmacy should document in writing the drug name, dosage form, strength, quantity and date transferred. The DEA registered reverse distributor who will destroy the controlled substances is

responsible for submitting a DEA Form-41 to DEA when the drugs have been destroyed. A DEA Form-41 should not be used to record the transfer of controlled substances between the pharmacy and the registered reverse distributor disposing the drugs.

"Blanket Authorization" for Destruction of Controlled Substances

DEA will issue a "Blanket Authorization" for destruction of controlled substances on a very limited basis to those registrants who are associated with hospitals, clinics or other registrants having to dispose of used needles, syringes or other injectable objects only. This limited exception is granted because of the probability that those objects have been contaminated by hazardous bodily fluids. The pharmacist should contact their local DEA Diversion Field Office for information about how to request such an authorization. DEA will evaluate requests for a blanket authorization based on the following guidelines:

1. Frequency of destruction (i.e., daily, weekly) and volume of drugs involved that warrant such authorization.
2. Method of destruction. Drugs must be destroyed in such a manner that they are beyond reclamation.
3. Registrant's past history.
4. Security at the pharmacy or registered location.
5. Name and position of the individual responsible for the destruction.

Those registrants granted blanket authorization to destroy controlled substances must complete DEA Form-41 (Registrants Inventory of Drugs Surrendered, see Appendix I).

Security Requirements

The DEA requires pharmacies to keep Schedules II, III, IV and V controlled substances in a locked cabinet or dispersed through the

non-controlled stock to deter theft. An electronic alarm system is recommended.

Request for Employment Waiver for Certain Pharmacy Employees

A pharmacy registrant (i.e., the registrant or corporation which owns the pharmacy) must not employ in a position which allows access to controlled substances, anyone who has been convicted of a felony relating to controlled substances, or who, at any time, has had an application for DEA registration denied, revoked, or surrendered for cause. "For cause" means surrendering a registration in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.

However, pharmacies desiring to employ an individual who meets this definition may request an exception to this requirement (see 21 CFR 1307.03) from DEA. The employer must have a waiver approved before hiring the applicant. A waiver request should be sent to DEA Headquarters, Office of Diversion Control, Washington, D.C. 20537.

A pharmacy registrant who applies for such a waiver should understand that the following factors will be considered:

1. A detailed description of the nature and extent of the applicant's past controlled substances violations.
2. Activities of the applicant since the violation.
3. Current status of the applicant's state licensure.
4. Extent of applicant's proposed access to controlled substances.
5. Registrant's proposed physical and professional safeguards to prevent diversion by the applicant if employed.
6. Status of employing registrant regarding handling of controlled substances.

7. Other pertinent information uncovered by DEA in its investigation of the applicant's or registrant's handling of controlled substances.
8. Such a waiver should not be considered unless there are valid reasons to believe that diversion is unlikely to occur.

Controlled Substance Theft or Loss

1. Notify DEA and Local Police

Immediately upon discovery of a theft or significant loss of controlled substances, a pharmacy, as required by regulation, must contact the nearest DEA Diversion Field Office (see Appendix T) by telephone, facsimile or by a brief written message explaining the circumstances. A pharmacy should also notify the local police as may be required by state law. If there is a question as to whether a theft has occurred or a loss is significant, a registrant should err on the side of caution and report it to DEA.

DEA must be notified directly. This requirement is not satisfied by reporting the theft or significant loss in any other manner. For example, a corporation which owns/operates multiple registered sites and wishes to channel all notifications through corporate management or any other internal department responsible for security must still provide notice directly to DEA "upon discovery" and keep a copy for its records.

2. Complete DEA Form-106

A pharmacy shall also complete a DEA Form-106 (Report of Theft or Loss of Controlled Substances). To obtain a DEA Form-106 (see Appendix J), contact the nearest DEA Diversion Field Office (see Appendix T). The DEA Form-106 will formally document the actual circumstances of the theft or significant loss and the quantities of controlled substances involved, once this information has been determined conclusively. The pharmacy should send the original DEA

Form-106 and a copy to the DEA Diversion Field Office and keep a copy for its records.

The DEA Form 106 must include the following information:

1. Name and address of firm (pharmacy)
2. DEA registration number
3. Date of theft
4. Name and telephone number of local police department notified
5. Type of theft (night break in, armed robbery, etc.)
6. Listing of symbols or cost code used by pharmacy in marking containers (if any)
7. Listing of controlled substances missing from theft or significant loss

3. If Investigation Finds No Theft or Loss

If after an investigation of the circumstances surrounding the theft or significant loss it is determined that no such theft or significant loss occurred, no DEA Form-106 need be filed.

However, the registrant should notify DEA in writing of this fact in order to resolve the initial report and explain why no DEA Form-106 was filed regarding the incident.

4. Registrant's Responsibility for Identifying "Significant Loss"

Although the CSA regulations do not define the term "significant loss," it is the responsibility of the registrant to use his/her best judgment to take appropriate action. A significant loss depends, in large part, on the business of the pharmacy and the likelihood of a rational explanation for a particular occurrence. What would constitute a significant loss for a pharmacy may be viewed as comparatively insignificant for a hospital or distributor.

Further, the loss of a small quantity of controlled substances, repeated over a period of time, may indicate a significant problem for a registrant, a problem which must be reported to DEA, even though the individual amounts of missing controlled substances are not, in and of themselves, significant. Registrants must report a loss upon discovery. In particular, a pharmacist should be alert for suspicious or unexplained losses. ***Any signs of a break in, physical entry or armed robbery should be reported.*** The burden of responsibility is on the registrant to identify what is a significant loss and make the required report to DEA.

Some factors to consider for determining significant loss include:

1. The schedule of the missing items.
2. The abuse potential of the missing items.
3. The abuse potential in your area of the missing substance.
4. The quantity missing (one tablet vs. one bottle or container).
5. Is this the first time this loss has occurred? Has a similar loss occurred before?
6. Was this loss reported to local law enforcement authorities?
7. If there is a question as to whether a loss is significant, a registrant should err on the side of caution and report it to DEA.

If it is determined that the loss is **not significant**, place a record of the occurrence in your theft and loss file for future reference.

In-Transit Loss

When all or part of a shipment disappears, or never reaches its intended destination, the supplier is responsible for reporting the in-transit loss of controlled substances to DEA. A pharmacy is responsible for reporting any loss of controlled substances after a pharmacist has signed for or taken custody of a shipment. If it's discovered after that point that an in-transit loss

or theft has occurred, the pharmacist must submit a DEA Form-106.

Breakage/Spillage

DEA further wishes to clarify that the breakage of controlled substances does not constitute a "loss" of controlled substances. When there is breakage, damage or spillage or some other form of destruction, any recoverable controlled substances must be disposed of according to DEA requirements. Damaged goods may be disposed of through shipment to a "reverse distributor" or by a DEA approved process as defined in **(Destruction of Controlled Substances)**. When this disposal occurs, it must be reported to DEA on a DEA Form-41 (*Registrants Inventory of Drugs Surrendered*, see Appendix I).

Controlled Substance Registrant Protection Act of 1984

Robberies, burglaries and assaults on pharmacists and other registrants by those seeking controlled substances are a serious problem in the United States. These crimes result in property loss, serious injury to professionals and bystanders, and trafficking which serves to fuel the drug abuse problem.

Federal Investigation

The Controlled Substances Registrant Protection Act of 1984 (CSRPA) provides for the federal investigation of pharmaceutical thefts and robberies if any of the following conditions are met:

1. Replacement cost of the controlled substances taken is \$500 or more.
2. A registrant or other person is killed or suffers "significant" bodily injury during the commission of the robbery or theft of a controlled substance.
3. Interstate or foreign commerce is involved in planning or executing the crime.

ordinary business records. (Recordkeeping requirements for prescriptions are detailed in the **Prescription Records** section.)

Readily retrievable means that:

1. Certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time.
2. And/or records are kept on which certain items are asterisked, redlined or in some other manner visually identifiable apart from other items appearing on the records.

Records that Must be Maintained

1. Official Order Forms (DEA Form-222).⁶
2. Power of Attorney authorization to sign Order Forms.
3. Receipts and invoices for Schedule III, IV, and V controlled substances as well as "threshold quantities"⁷ of List I chemicals.
4. All inventory records of controlled substances, including the initial and biennial inventories.
5. Records of controlled substances distributed or dispensed (i.e., prescriptions) and threshold amounts of List I chemicals distributed.
6. Report of Theft or Loss (DEA Form-106).
7. Inventory of Drugs Surrendered for Disposal (DEA Form-41).
8. Records of transfers of controlled substances between pharmacies.
9. DEA registration certificate.

⁶ DEA's Official Order Forms are the required records of receipt and sale for Schedule II controlled substances

⁷ The quantity of a particular chemical, above which recordkeeping and other control provisions of the CSA apply. See Appendix B "List I Chemicals with Domestic Threshold Amounts"

Penalties Upon Conviction

The perpetrator convicted of violating the CSRPA's provisions is subject to the following penalties:

1. Conviction for commission of burglary or robbery can result in a maximum \$25,000 fine and/or 20 years imprisonment.
2. Conviction for use of a dangerous weapon in the commission of the crime can result in a maximum \$35,000 fine and/or 25 years imprisonment.
3. If death results from the crime, the convicted person can receive a maximum \$50,000 fine and/or life imprisonment.

Recordkeeping Requirements

Every pharmacy must maintain complete and accurate records on a current basis for each controlled substance purchased, received, distributed, dispensed or otherwise disposed of. All records of controlled substances must be maintained for two years. This recordkeeping system allows a controlled substance to be tracked from the time it is manufactured to the time it is dispensed to the ultimate user. (Recordkeeping requirements for List I Chemicals are contained in the Chemical Requirements section.)

All records concerning controlled substances must be maintained for at least two years for inspection and copying by duly authorized DEA officials. Records and inventories of Schedule II controlled substances must be maintained separately from all other records of the registrant. All records and inventories of **Schedule III, IV and V** controlled substances must be maintained either separately from all other records or in such a form that the information required is readily retrievable from the

Central Recordkeeping

A registrant desiring to maintain shipping and financial records at a central location other than the registered location must notify the nearest DEA Diversion Field Office (see Appendix T). Unless the registrant is informed by the DEA that the permission to keep central records is denied, the registrant may begin maintaining central records 14 days after notifying DEA. Central recordkeeping requirements are described in 21 CFR, 1304.04. Central recordkeeping permits are no longer issued by the DEA.

Prescription Records

Pharmacies have three options for filing prescription records under the Code of Federal Regulations. If there is a conflict between federal and state requirements for filing prescriptions, DEA recognizes that the pharmacy must choose a filing system that would comply with both federal and state law (Title 21 USC, Section 903).

All prescription records must be **readily retrievable** for DEA inspection. Controlled substance prescriptions must be filed in one of the following three ways:

Option 1 (Three separate files)

- A file for Schedule II drugs dispensed,
- A file for Schedule III, IV and V drugs dispensed, and
- A file for prescription orders for all noncontrolled drugs dispensed.

Option 2 (Two separate files)

- A file for all Schedule II drugs dispensed,
- A file for all other drugs dispensed (noncontrolled and those in Schedule III, IV and V). If this method is used, a prescription for a Schedule III, IV and V drug must be made readily retrievable by use of a red "C" stamp not less than one inch high.⁸

Option 3 (Two separate files)

- A file for all Schedule II-V controlled substances. If this method is used, a prescription for a Schedule III, IV and V drug must be made readily retrievable by use of a red "C" stamp not less than one inch high.⁸
- A file for prescription orders for all noncontrolled drugs dispensed.

Inventory Requirements

Inventory means a complete and accurate list of all stocks and forms of controlled substances in the possession of the registrant as determined by an actual physical count. The CFR also requires that all inventories be maintained at the registered location in a readily retrievable manner for at least two years for copying and inspection. In addition, the inventory of Schedule II controlled substances must be kept separate from those for all other controlled substances.

Initial Inventory

When issued a DEA registration, a registrant must take an initial inventory, which is an actual physical count of all controlled substances in their possession. If there are no stocks of controlled substances on hand, the registrant should make a record showing a zero inventory. ***There is no requirement to submit a copy of the inventory to the DEA.***

The Code of Federal Regulations (CFR) requires that the inventory include:

1. The inventory date.
2. The time the inventory is taken (i.e., opening or close of business).

⁸ If a pharmacy has an electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed and date filled, then the requirements to mark the hard copy prescription with a red "C" is waived.

3. The drug name.
4. The drug strength.
5. The drug form (e.g., tablet, capsule, etc.).
6. The number of units/volume.
7. The total quantity.

DEA recommends that the inventory record include:

1. The name, address and DEA registration number of the registrant.
2. The signature of the person or persons responsible for taking the inventory.

Biennial Inventory

Following the initial inventory, the registrant is required to take a biennial inventory (every two years), which requires the same information as the initial inventory (see list above) of all controlled substances on hand. The biennial inventory may be taken on any date which is within two years of the previous inventory date. There is no requirement to submit a copy of the inventory to DEA.

When taking the inventory of Schedule II controlled substances, an actual physical count must be made. For the inventory of Schedules III, IV and V controlled substances, an estimated count may be made. An actual physical count must be made if the container holds more than 1,000 dosage units and has been opened.

Inventorying Newly Scheduled Controlled Substances

When a drug not previously controlled is scheduled, the drug must be inventoried as of the effective date of scheduling.

Inventory of Drugs for Destruction or No Longer Saleable

Each controlled substance that is (1) damaged, defective, or impure and is awaiting disposal, (2) held for quality control purposes, or (3) maintained for extemporaneous compoundings, must be inventoried.

The Code of Federal Regulations (CFR) requires that the inventory include:

1. The inventory date.
2. The drug name.
3. The drug strength.
4. The drug form (e.g., tablet, capsule, etc.).
5. The total quantity or total number of units/volume.
6. The reason why the substance is being maintained.
7. Whether substance is capable of being used in the manufacture of any controlled substance in finished form.

Ordering Controlled Substances

Schedule II Substances

Only Schedule I and II controlled substances are ordered with a DEA Form-222 (Official Order Form, see Appendix H). An Official Order Form is required for each distribution, purchase or transfer of a Schedule II controlled substance.

When a controlled substance has been transferred by DEA from Schedule II to another Schedule at the federal level, in many states it remains in Schedule II pending any legislative or administrative actions that may result from the federal action. Many states require that transactions involving substances that they classify as Schedule II be made via DEA Form-222 Official Order Forms. Where federal and state laws or regulations conflict, the stricter applies. When the use of DEA Form-222 Official Order Forms for the transfer of a controlled substance is not required

under federal law, its use as mandated by these states does not violate federal law and is therefore permitted.

Requesting Official Order Forms

Official Order Forms can be initially requested by checking "block 3" on the application for new registration (DEA Form-224). There is no charge. Send the form to:

**Drug Enforcement Administration
Registration Unit
Central Station
P.O. Box 28083
Washington, D.C. 20038-8083**

Once a registrant has received Official Order Forms (DEA Form-222), a separate requisition form (DEA Form-222a) will be mailed to the registrant to request additional Official Order Forms. The registrant may also request Official Order Forms by calling either the DEA Headquarters Registration Unit (toll free: 1-800-882-9539) or the nearest DEA Registration Field Office (See Appendix T).

Each book of DEA Official Order Forms consists of seven sets of forms. Each pharmacy is provided a maximum of six books at one time unless its needs exceed this limit. In such a case, the pharmacy should contact the DEA Registration Field Office serving their state (Appendix T).

Completing Official Order Forms

When ordering Schedule II substances, the pharmacist is responsible for filling in the number of packages, the size of the package and the name of the item. Each Official Order Form must be signed and dated by a person authorized to sign a registration application. (See Power of Attorney to Sign an Official Order Form) When the items are received, the pharmacist must document on the purchaser's copy (copy 3) the actual number of packages received and the date received.

Official Order Forms must be maintained separately from the pharmacy's other business records. However, this does not

preclude a registrant from attaching a copy of the supplier's invoice to the related Order Form.

The Code of Federal Regulations requires that the Official Order Form must be "complete, legible, and properly prepared, with no signs of alteration, erasure or change of any description." A supplier may refuse to accept an order for any of these reasons. However, DEA has acknowledged some minor changes or alterations may be accepted by a supplier. For example, suppliers may correct Official Order Forms that have:

- Minor errors, which lack inconsequential information or
- An incorrect date unintentionally annotated by the purchaser.

If an order is refused, the supplier should return Official Order Form copies 1 and 2 to the purchaser with a statement explaining the reason the order was refused.

DEA policy does not preclude the substitution of identical products differing in packaging size from those initially ordered, provided that the actual quantity received does not exceed the amount initially ordered and that the National Drug Code number reflected is that of the actual product shipped. For example, a distributor may substitute 5 bottles of 100, 2mg tablets for 1 bottle of 500, 2mg tablets or any variation thereof.

Power of Attorney to Sign an Official Order Form

Any registrant (pharmacy) may authorize one or more individuals, whether or not they are located at the registered location, to obtain and execute Official Order Forms by granting a power of attorney to each such individual. ***The power of attorney must be signed by the same person who signed the most recent application for registration or renewal registration, as well as the individual being authorized to obtain and execute Official Order Forms.***

The power of attorney may be revoked at any time by the person who signed the power of attorney. It is necessary to grant a new power of attorney when the pharmacy completes a renewal

registration, only if the renewal application is signed by a different person. The power of attorney should be filed with executed Official Order Forms as a readily retrievable record. The power of attorney is **not submitted to DEA**.

Suggested formats for granting and revoking power of attorney follow:

POWER OF ATTORNEY FOR DEA ORDER FORMS

(Name of registrant)

(Address of registrant)

(DEA registration number)
I, _____ (name of person granting power), the undersigned, who is authorized to sign the current application for registration of the above named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these present, do make, constitute, and appoint _____ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for books of official order forms and to sign such order forms in requisition for Schedule I and II controlled substances, in accordance with Section 308 of the Controlled Substances Act (21 U.S.C. 828) and part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

(Signature of person granting power) I, _____ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

Witnesses:

1. _____
2. _____

Signed and dated on the ____ day of _____ in the year ____ at _____.

NOTICE OF REVOCATION OF POWER OF ATTORNEY

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact _____ this same day.
(Signature of person revoking power)

Witnesses:

1. _____
2. _____

Signed and dated on the ____ day of _____, in the year ____ at _____.

Lost or Stolen Order Forms

When the pharmacist has not received a shipment of controlled substances, he/she should first contact the supplier to determine whether the original DEA Form-222 was received. If the original order form has been lost or stolen, the pharmacist must complete a second order form so the supplier can fill the original order. The pharmacist must also prepare a statement which includes the first order form's serial number and date, and verify that the drugs ordered were never received. Attach a copy of the statement to the second order form that is sent to the supplier. The pharmacist must keep a copy of the statement with copy 3 from the first and second order forms.

A pharmacy, upon discovery of the loss or theft of unused order forms, must immediately report the loss to the nearest DEA Diversion Field Office (Appendix T), and provide the serial numbers of each lost or stolen order form. If an entire book or multiple books of order forms are lost or stolen, and the serial numbers of the missing forms cannot be identified, the pharmacist must report the approximate date of issuance (in lieu of the serial numbers) to the DEA. If an unused order form reported stolen or

lost is later recovered or found, the pharmacy must immediately notify the nearest DEA Diversion Field Office.

Schedule III-V Substances

The registrant (pharmacy) must keep a receipt (i.e., invoice or packing slip) on which they record the date the drugs were received and confirm that the order is accurate. These receipts must be maintained in a readily retrievable manner for inspection by the DEA.

Prescription Requirements

To dispense controlled substances, a pharmacist must know the requirements for a valid prescription which are described in this section. A prescription is an order for medication which is dispensed to or for an ultimate user. A prescription is not an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to an inpatient for immediate administration in a hospital is not a prescription.)

A prescription for a controlled substance must be dated and signed on the date when issued. The prescription must include the patient's full name and address, and the practitioner's name, address, and registration number. The prescription must also include the drug name, strength, dosage form, quantity prescribed, directions for use, and number of refills. Where an oral prescription is not permitted, a prescription must be written in ink or indelible pencil or typewritten and must be manually signed by the practitioner. An individual (i.e., secretary or nurse) may be designated by the practitioner to prepare prescriptions for his/her signature. The practitioner is responsible for making sure that the prescription conforms in all essential respects to the law and regulations.

Who May Issue

A prescription order for a controlled substance may be issued only by a physician, dentist, podiatrist, veterinarian, mid-level practitioner or other registered practitioner who is:

1. Authorized to prescribe controlled substances by the jurisdiction in which he/she is licensed to practice; and
2. Registered with DEA or exempted from registration (i.e., Public Health Service and Bureau of Prison physicians).

Verification of Practitioner Registration

Construction of Valid DEA Registration Numbers for Practitioners

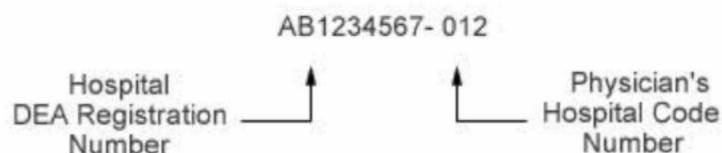
Knowing how a DEA registration number is constructed can be a useful tool for recognizing a forged prescription. (For additional information regarding forged prescriptions, see Appendix O) Prior to October 1, 1985, DEA registration numbers for physicians, dentists, veterinarians and other practitioners started with the letter A. New registration numbers issued to practitioners after that date begin with the letter B. Registration numbers issued to mid-level practitioners begin with the letter M. The first letter of the registration number is followed by the first letter of the registrant's last name. (e.g., J for Jones or S for Smith), and then a computer generated sequence of seven numbers (such as MJ3614511). (See Mid-Level Practitioner [MLP], regarding their authority to prescribe controlled substances.)

Practitioner's Use of a Hospital's DEA Registration Number

An individual practitioner (e.g., intern, resident, staff physician, mid-level practitioner) who is an agent or employee of a hospital or other institution may, when acting in the usual course of business or employment, administer, dispense or prescribe controlled substances under the registration of the hospital or other institution in which he or she is employed, provided that:

1. The dispensing, administering, or prescribing is in the usual course of professional practice;
2. The practitioner is authorized to do so by the state in which he or she is practicing;

3. The hospital or institution has verified that the practitioner is permitted to dispense, administer or prescribe controlled substances within the state;
4. The practitioner acts only within the scope of employment in the hospital or institution;
5. The hospital or institution authorizes the practitioner to dispense or prescribe under its registration and assigns a specific internal code number for each practitioner so authorized (See example of a specific internal code number below);



6. A current list of internal codes and the corresponding individual practitioners is to be kept by the hospital or other institution. This list is to be available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner. **Pharmacists should contact the hospital or other institution for verification if they have any doubts in dispensing such a prescription.**

Exception to the Registration Requirement for Public Health Service or Bureau of Prisons Personnel

Any official of the Public Health Service or Bureau of Prisons who is authorized to prescribe, dispense or administer, but not to procure or purchase, controlled substances in the course of his or her official duties, is not required to be registered

with DEA. Such officials must specify their agency and service identification number of the issuing official in lieu of a DEA registration number on any prescriptions for controlled substances. The service identification number for a public Health Service employee is his/her Social Security Number.

Registration Requirement for Military Personnel

The requirement for registration is waived for military physicians who prescribe, dispense, or administer, but do not procure or purchase, controlled substances in the course of official duties. Military physicians issuing prescriptions must indicate the branch of service or agency and the service identification number in lieu of the registration number required on prescriptions. Such prescriptions may be filled off base at community pharmacies.

Many computer systems at pharmacies are programmed to accept a DEA registration number and the use of a service identification number causes delays when dispensing a prescription. As a result, DEA has begun to issue DEA registrations to active duty military physicians to expedite the filling of prescriptions at community pharmacies. Therefore, a prescription from a military physician must contain either the service identification number or a DEA registration number of the prescriber.

DEA will not issue registrations to mid-level practitioners (MLP) in the military unless they are specifically licensed in the state where they are stationed and the state allows the MLP to dispense controlled substances.

Physicians and MLPs must obtain a separate DEA registration for any work outside of official duties and they must follow the requirements of the jurisdiction in which they are performing the non-official work.

Mid-Level Practitioners

Mid-level practitioners (MLP) are registered and authorized by the DEA and the state in which they practice to dispense, administer and prescribe controlled substances in the course of professional practice. Examples of MLPs include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, physician assistants, optometrists, ambulance services, animal shelters, veterinarian euthanasia technicians, nursing homes and homeopathic physicians.

MLPs may receive individual DEA registration granting controlled substance privileges. However, such registration is contingent upon authority granted by the state in which they are licensed. DEA registers MLPs whose states clearly authorize them to prescribe, dispense and administer controlled substances in one or more schedules. The fact that an MLP has been issued a valid DEA registration number (beginning with the letter M) will be evidence that he/she is authorized to prescribe, dispense and/or administer at least some controlled substances.

However, it will still be incumbent upon the pharmacist who fills the prescription to ensure that the MLP is prescribing within the parameters established by the state in which he/she practices. MLP authority to prescribe controlled substances varies greatly by state. Check with your state licensing or controlled substances authority to determine which MLP disciplines are authorized to prescribe controlled substances in your state.

Purpose of Issue

To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of sound professional practice. The practitioner is responsible for the proper prescribing and dispensing of controlled substances. However, a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order for controlled substances which purports to be a valid prescription, but is not issued in the usual course of

professional treatment, or for legitimate and authorized research, is not a valid prescription within the meaning and intent of the CSA. The individual who knowingly dispenses such a purported prescription, as well as the individual issuing it, will be subject to criminal and/or civil penalties and administrative sanctions.

A prescription may not be issued in order for an individual practitioner to obtain a supply of controlled substances for the purpose of general dispensing to his/her patients. Therefore, a prescription written for office stock or "medical bag" use is not valid.

Schedule II Substances

Schedule II substances require a written prescription which must be signed by the practitioner. There is no time limit when a Schedule II prescription must be filled after being signed by the physician. However, the pharmacist must determine that the prescription is still needed by the patient (e.g., a narcotic prescription filled several weeks after being written.) Federal regulations place no quantity limits on any prescriptions. For Schedule II substances, an oral order is only permitted in an emergency situation. (See Emergency Dispensing of Schedule II Controlled Substances.)

Refills

Refilling a Schedule II prescription is prohibited.

Facsimile Prescriptions for Schedule II Substances

In order to expedite filling the prescription, a prescriber may fax the Schedule II prescription to the pharmacy, as authorized in a final rule published in May 1994. This rule requires that the original Schedule II prescription be presented to the pharmacist and verified against the facsimile at the time the controlled substance is actually dispensed. The pharmacist must

make sure the original document is properly annotated and filed with the records that are required to be kept.

In an emergency, a practitioner may transmit a prescription for a Schedule II controlled substance by facsimile or telephone to the pharmacy, and the pharmacist may dispense the prescription. However, the prescribing practitioner must provide a written, signed prescription to the pharmacist within seven days, and the pharmacist must notify DEA if he/she does not receive the prescription. (See Emergency Dispensing of Schedule II Controlled Substances.)

Exceptions for Schedule II Facsimile Prescriptions

DEA also granted three exceptions to the facsimile prescription requirements for Schedule II controlled substances. The facsimile of a Schedule II prescription may serve as the original prescription as follows:

1. A practitioner prescribing Schedule II narcotic controlled substances for a patient undergoing home infusion/intravenous (IV) pain therapy, may transmit the prescription by facsimile. The practitioner's agent may also transmit the prescription to the pharmacy. The pharmacy will consider the facsimile prescription a "written prescription" and no further prescription is required. All normal requirements of a legal prescription must be followed.
2. Practitioners prescribing Schedule II controlled substances for patients in Long Term Care Facilities (LTCF), which are normally filled and delivered to the facility by the pharmacy, may transmit a prescription by facsimile to the dispensing pharmacy. The practitioner's agent may also transmit the prescription to the pharmacy. ***The facsimile prescription serves as the original written prescription for the pharmacy. No further original prescription is required.***

3. A practitioner prescribing a Schedule II narcotic substance for **a patient in hospice care** as certified by Medicare under Title XVIII or licensed by the state, may transmit a prescription to the dispensing pharmacy by facsimile regardless of whether the patient resides in a hospice facility or other care setting. The practitioner's agent may also transmit the prescription to the pharmacy. ***The practitioner will note on the prescription that it is for a hospice patient. The facsimile serves as the original written prescription.***

Schedule III-V Substances

A prescription for controlled substances in Schedules III, IV and V issued by a practitioner may be communicated either orally, in writing or by facsimile to the pharmacist and may be refilled if so authorized on the prescription.

Refills

Schedule III and IV controlled substances may be refilled if authorized on the prescription. However, the prescription may only be refilled up to five times within six months after the date of issue. After five refills or after six months, whichever occurs first, a new prescription is required. A patient is permitted to request a refill of an existing Schedule III-V controlled substance prescription by sending an e-mail to the pharmacy or by telephone.

Schedule V controlled substances may only be refilled as authorized on the prescription by the prescribing practitioner.

When a prescription for any controlled substance in Schedule III, IV, or V is refilled, the following information must be entered on the back of the prescription: the dispensing pharmacist's initials, the date the prescription was refilled, and the amount of drug dispensed on the refill. If the pharmacist only initials and dates the back of the prescription, the pharmacist will be deemed to have dispensed a refill for the full face amount of the prescription.

Computerization of Prescription Information

A pharmacy is permitted to use a data processing system as an alternative to the manual method for the storage and retrieval of prescription order refill information for Schedules III, IV and V controlled substances.

The computer system must provide on-line retrieval of original prescription information for those prescriptions which are currently authorized for refill. The information must include, but is not limited to the original prescription number, date of issuance, full name and address of the patient, the prescriber's name, address, and DEA registration number; the name, strength, dosage form and quantity of the controlled substance prescribed; and the total number of refills authorized by the prescriber.

In addition, the computer system must provide on-line retrieval of the current refill history for Schedule III, IV, or V controlled substance prescriptions. This information must include, but is not limited to: the name of the controlled substance, the date of refill, the quantity dispensed, the dispensing pharmacist's identification code, or name/initials for each refill, and the total number of refills dispensed to date for that prescription. ***The pharmacist must verify and document that the refill data entered into the system is correct.*** All computer generated prescription/refill documentation must be stored in a separate file at the pharmacy and be maintained for a two-year period from the dispensing date. To meet the CFR recordkeeping requirements, the pharmacy's computer must comply with the following guidelines:

1. If the system provides a hard copy printout of each day's controlled substance prescription refills, each pharmacist who refilled those prescriptions shall verify their accuracy by signing and dating the printout as he/she would sign a check or legal document.
2. This printout must be provided to each pharmacy which uses the computer system within 72 hours of the date on

which the refill was dispensed. The printout must be verified and signed by each pharmacist who dispensed the refills.

3. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file in which each pharmacist involved in the day's dispensing signs a statement verifying that the refill information entered into the computer that day has been reviewed by him/her and is correct.
4. A pharmacy computer system shall have the capability of printing out any refill data which the pharmacy must maintain under the Controlled Substances Act. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance, by either brand or generic name or both, dispensed by the pharmacy. Such a printout must include:
 - Prescribing practitioner's name.
 - Patient's name and address.
 - Quantity dispensed on each refill.
 - Dispensing date for each refill.
 - Name or identification code of the dispensing pharmacist.
 - Original prescription number.

In any computerized system employed by a user pharmacy, the central recordkeeping location must be capable of providing a printout to a requesting pharmacy of the above information within 48 hours.
5. In case a pharmacy's computer system experiences downtime, the pharmacy must have a back-up procedure to document in writing refills of Schedule III, IV and V substances. This procedure must ensure that refills are authorized by the original prescription, that the maximum number of refills has not been exceeded, and that all required data is retained for on-line entry as soon as possible.

6. A pharmacy may use only one of the two systems described (i.e., manual or computer).

Facsimile Prescriptions for Schedule III-V Substances

Prescriptions for Schedules III-V controlled substances may be transmitted by facsimile from the practitioner or an employee or agent of the individual practitioner. The facsimile is considered to be equivalent to an original prescription.

Telephone Authorization for Schedule III-V Prescriptions

Only the practitioner can prescribe controlled substances and this authority cannot be delegated to anyone else. A prescription issued by a practitioner may be called in to a pharmacist by the practitioner or an employee or agent of the individual practitioner. It is the pharmacist's responsibility to insure that these telephone prescriptions are valid and properly authorized by the practitioner. (See Pharmacist's Guide to Prescription Fraud, Appendix O)

Transfer of Prescription Information

DEA will allow the transfer of original prescription information for Schedules III, IV and V controlled substances for the purpose of refill dispensing between pharmacies on a one time basis, if permissible under state law. (See **Prescription Requirements**.)

Pharmacies electronically sharing a real time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization. Such systems must contain the information required for a valid prescription.

Prescription Monitoring Programs

A prescription monitoring program is a state-administered data collection system used to gather prescription information. This information may be made available to state and federal investigators on a need-to-know basis.

Many states have adopted either a multiple copy prescription program or an electronic data transmission system because they have proven to be an effective tool for detecting pharmaceutical diversion, for developing pharmacist and physician medical education programs that heighten awareness about diversion, prescription drug abuse, drug trends, and for tracking effective use of prescription medication within a state. For the pharmacist, the data can be used to identify potential "doctor shoppers," and those who attempt to obtain controlled substances by fraud, forgery or deceit.

In the states that have adopted these programs, a large part of their success has been attributed to the pharmacists' participation. DEA strongly endorses prescription monitoring programs and works closely with the states on these programs.

Dispensing Requirements

Required Information for Prescription Labels

The pharmacist dispensing a prescription for a controlled substance must affix to the container a label showing the pharmacy name and address, the serial (prescription) number, date of initial dispensing, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained on the prescription as required by law.

Federal Food and Drug Administration (FDA) regulations require that the label of any drug listed as a "Controlled Substance" in Schedules II, III, or IV of the Controlled Substances Act must, when dispensed to or for a patient, contain the following

warning: CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

Schedule II Substances

A pharmacist may dispense a Schedule II controlled substance, which is a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, only pursuant to a written prescription signed by the practitioner, **except in an emergency situation as described in the following section.**

Emergency Dispensing

Emergency means that the immediate administration of the drug is necessary for proper treatment of the intended ultimate user, that no alternative treatment is available (including a drug which is not a Schedule II controlled substance), and it is not possible for the prescribing practitioner to provide a written prescription for the drug at that time.

In a bona fide emergency, a practitioner may telephone a Schedule II prescription to the pharmacy or transmit the prescription by facsimile to the pharmacy, and the pharmacist may dispense the prescription provided that:

1. The drug prescribed and dispensed must be limited to the amount needed to treat the patient during the emergency period. Prescribing or dispensing beyond the emergency period must be pursuant to a written prescription order.
2. The prescription order must be immediately reduced to writing by the pharmacist and must contain all information, except for the prescribing practitioner's signature.
3. If the prescriber is not known to the pharmacist, the pharmacist must make a reasonable effort to determine that the phone authorization came from a valid practitioner, by verifying the practitioner's telephone number with that

listed in the directory and by making other good faith efforts to insure proper identity.

4. Within seven days after authorizing an emergency telephone prescription, the prescribing practitioner must furnish the pharmacist a written, signed prescription for the controlled substance prescribed. The prescription must have written on its face "Authorization for Emergency Dispensing." The written prescription may be delivered in person or by mail, which must be postmarked within the seven day period. Upon receipt, the dispensing pharmacist must attach this written prescription to the oral prescription reduced to writing by the pharmacist. By law the pharmacist must notify the nearest DEA Diversion Field Office if the prescriber fails to provide a written prescription within seven days. If the pharmacist fails to do so, his/her authority to dispense without a written prescription will be void.

Partial Dispensing

The pharmacist may partially dispense a prescription for a Schedule II controlled substance if he/she is unable to supply the full quantity in a written or emergency oral (telephone) prescription, provided the pharmacist notes the quantity supplied on the front of the written prescription (or on a written record of the emergency oral prescription). The remaining portion may be dispensed within 72 hours of the first partial dispensing. However, if the remaining portion is not or cannot be dispensed within the 72-hour period, the pharmacist must notify the prescribing practitioner. No further quantity may be supplied beyond the 72 hours, except on a new prescription.

Exception for Schedule II Prescriptions at Long Term Care Facilities

An exception has been made for patients in Long Term Care Facilities (LTCF) and patients who have been diagnosed with a terminal illness. If there is any question whether a patient

may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" will be deemed to have been filled in violation of the CSA. In such cases, prescriptions may be filled in partial quantities, including single dosage units. For each partial filling, the pharmacist must note on the prescription (or other uniformly maintained, readily retrievable record) the date the prescription was partially filled, the quantity dispensed, the remaining quantity and the identification of the dispensing pharmacist. Such prescriptions are valid for a maximum of 60 days from the date of issue, unless terminated earlier by discontinuance of the medication.

Internet Pharmacy

The actual physical location of the pharmacy which purchases, stores, and dispenses controlled substances pursuant to prescription orders processed by the Internet site must be registered with DEA. The web site itself would not require a separate registration unless it is the same physical location, since the web site does not store or dispense controlled substances. For example, some Internet pharmacies maintain a central pharmacy warehouse site and offices where prescriptions are verified and substances shipped; this location must be registered with DEA as a retail pharmacy. Other Internet sites allow patients to pick up their prescriptions for controlled substances from a local pharmacy; these pharmacies must be registered with DEA. In this case, the Internet "pharmacy" has no obligations under DEA regulations because the responsibility for assuring compliance with DEA regulations rests with the actual pharmacy where controlled substances are dispensed.

The pharmacy must have a license from the state in which the controlled substances are stored and dispensed and, in most

instances, from any state in which you plan to conduct business with customers. Pharmacists should also be aware that many states require licenses for the web site itself since these sites often provide services like patient counseling. Being an Internet pharmacy does not change the pharmacy's responsibilities under DEA regulations. The pharmacy is still authorized to sell controlled substances only when there is a valid prescription from a DEA-registered practitioner who issued the prescription in the usual course of his or her professional practice.

A pharmacist may dispense a Schedule II controlled substance only after the patient or prescriber provides an original signed prescription prior to dispensing. The label on the prescription filled must indicate the location that dispensed the controlled substance.

Some Internet pharmacies have doctors who prescribe substances based on an on-line questionnaire. Federal law requires that "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice" (21 CFR 1306.04(a)). Every state separately imposes a similar acting requirement under its laws. Under Federal and state law, for a doctor to be acting in the usual course of professional practice, there must be a bona fide doctor/patient relationship.

For purpose of state law, many state authorities, with the endorsement of medical societies, consider the existence of the following four elements as an indication that the legitimate doctor/patient relationship has been established:

- A patient has a medical complaint;
- A medical history has been taken;
- A physical examination has been performed; and
- Some logical connection exists between the medical complaint, the medical history, the physical examination, and the drug prescribed.

Electronic Transmission of Prescriptions

DEA is currently engaged in a project to establish the requirements for secure electronic transmission of all controlled substance prescriptions between the practitioner and the pharmacy.

Proposed security requirements include:

- Authentication of the prescriber
- Content integrity
- Non-repudiation of involvement by parties to a transaction

Schedule III-V Controlled Substance Prescriptions

A pharmacist may dispense a Schedule III, IV, or V controlled substance having received either a written prescription signed by a practitioner, a facsimile of that prescription transmitted by the practitioner or his/her agent to the pharmacy, or an oral prescription made by an individual practitioner. The pharmacist must promptly reduce the oral prescription to writing, including all required information. At this time, DEA does not permit a prescription received via the internet to be filled. If prescription information is received via the internet, the pharmacist must contact the prescriber via telephone and receive an oral prescription for the controlled substance including the full name and address of the patient, the drug name, strength, dosage form, quantity, prescribed directions for use, and the name, address, and registration number of the practitioner. The pharmacist must then immediately reduce the oral prescription to writing.

Partial Dispensing

The pharmacist may partially dispense a prescription for a Schedule III-V controlled substance if the pharmacist notes the quantity dispensed and initials the back of the prescription order. The partial dispensing may not exceed the total amount

authorized in the prescription order. The dispensing of all refills must be within the six month limit. It is permissible to dispense a prescription for a quantity less than the face amount prescribed resulting in the actual number of dispensings being greater than the number of refills indicated on the prescription.

Dispensing Without a Prescription

In states where limited quantities of Schedule V preparations may be sold over-the-counter, the pharmacist is responsible for making sure that such sales comply with state law. Schedule V controlled substances or any controlled substance listed in Schedule II, III or IV which is not a prescription item under the Federal Food, Drug, and Cosmetic Act may be dispensed without a prescription at retail provided that:

1. Such distribution is made only by a pharmacist and not by a non-pharmacist employee, even if under the direct supervision of a pharmacist. However, after the pharmacist has fulfilled professional and legal responsibilities, the actual cash, credit transaction or delivery may be completed by a non-pharmacist.
2. Because there is no physician determining the medical necessity for a Schedule V over-the-counter product, the pharmacist must ensure the medical necessity of the need for the product.
3. Not more than 240 ml. (8 fluid ounces) or not more than 48 solid dosage units of any substance containing opium, not more than 120 ml. (4 fluid ounces) or not more than 24 solid dosage units of any other controlled substance, may be distributed at retail to the same purchaser in any given 48-hour period without a valid prescription.

4. The purchaser at a retail outlet is at least 18 years of age.
5. For the retail purchase of a Schedule V controlled substance, every customer the pharmacist does not know should be required to provide suitable identification, including proof of age, where appropriate.
6. A Schedule V bound record book is maintained which contains the name and address of the purchaser, name and quantity of controlled substance purchased, date of each sale, and initials of the dispensing pharmacist. This record book must be maintained for a period of two years from the date of the last transaction entered in such record book, and it must be made available for inspection and copying by officers of the United States, as authorized by the U.S. Attorney General.
7. Other federal, state or local law does not require a prescription.

Delivery of a Controlled Substance or Drug Product Containing Listed Chemicals to Persons in Another Country

Controlled substances that are dispensed pursuant to a legitimate prescription may not be delivered or shipped to individuals in another country without proper authorization. Any such delivery or shipment is an export under the CSA, and cannot be conducted unless the person sending the controlled substances:

1. Has registered with DEA as an "exporter" (see 21 CFR 1301 or 21 CFR 1309 for chemicals), and
2. Has obtained the necessary permit(s), or submitted the necessary declaration(s) for export as outlined in 21 CFR 1312 or 21 CFR 1313 for chemicals.

Central Fill Pharmacy

A "central fill" pharmacy fills prescriptions for controlled substances on behalf of retail pharmacies with which central fill pharmacies have a contractual agreement to provide such services or with which the pharmacies share a common owner. When one retail pharmacy receives a prescription and a second pharmacy prepares and subsequently delivers the controlled substance medication to the first retail pharmacy for dispensing to the patient, the second pharmacy is engaging in a "central fill activity". Records must be maintained by both the central fill pharmacy and the retail pharmacy that completely reflect the disposition of all controlled substance prescriptions dispensed. Central fill pharmacies are required to comply with the same security requirements applicable to retail pharmacies including the general requirement to maintain effective controls and procedures to guard against theft and diversion of controlled substances. Retail pharmacies that also perform central fill activities are allowed to do so without a separate DEA registration, separate inventories, or separate records.

Central fill pharmacies are permitted to prepare both initial and refill prescriptions, subject to all applicable state and federal regulations. Only a licensed pharmacist may fill the prescription. Both the pharmacist employed by the pharmacy and the pharmacist who dispenses the prescription to the patient have a corresponding responsibility to ensure that the prescription was issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice and otherwise in the manner specified by DEA regulations.

A central fill pharmacy will not be permitted to prepare prescriptions provided directly by the patient or individual practitioner or to mail or otherwise deliver a filled prescription directly to a patient or individual practitioner. Retail pharmacies are permitted to transmit prescription information to a central fill pharmacy in two ways. First, a facsimile of a prescription for a controlled substance in Schedule II-V may be provided by the retail pharmacy to the central fill pharmacy. The retail pharmacy must maintain the original hard copy of the prescription and the central fill pharmacy must maintain the facsimile of the

prescription. DEA is also allowing for the prescription information to be transmitted electronically by the retail pharmacy to the central fill pharmacy. Both pharmacies must maintain the prescription information in a readily retrievable manner and comply with all applicable federal and state recordkeeping requirements.

Long Term Care Facilities

A Long Term Care Facility (LTCF) is defined in the Code of Federal Regulations as a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients. In most cases, these facilities are not registered with DEA. Yet these care facilities routinely maintain controlled substances issued via prescription to their residents. These controlled substances are already outside the CSA closed drug distribution system since they have been dispensed to the ultimate user (i.e., patient). LTCFs frequently need to dispose of unused medications due to a change in patient medication or the patient's demise. For drug disposal instructions, contact your nearest DEA Diversion Field Office (see Appendix T). In most cases these LTCFs are regulated by state agencies and other federal mandates (FDA, Federal Nursing Home Guidelines, etc.). DEA is aware of the issues currently facing most LTCFs concerning the dispensing and handling of controlled substances. These are affected by a variety of state laws and circumstances. Pharmacists should check with their state agency for guidelines concerning controlled substances at LTCFs.

In this manual, regulations concerning LTCFs are also found in the Prescription Requirements section under Exceptions for Schedule II Facsimile Prescription, and in the Dispensing section under Exception for Schedule II Prescriptions at Long Term Care Facilities.

Emergency Kits for Long Term Care Facilities

The DEA has issued a policy statement which provides individual state licensing and regulatory boards with general guidelines for establishing specific rules concerning controlled substances used in emergency kits at Long Term Care Facilities. For a copy of this policy statement, see Guidelines for Emergency Kits in Long Term Care Facilities, Appendix R.

Narcotic Treatment Programs

The Narcotic Addict Treatment Act of 1974 is the law that governs the use of narcotics and the treatment of addiction in the United States. In addition, the law designates which government agencies have responsibility for narcotic treatment programs, defines the terms "maintenance" and "detoxification," and explains who has to register to treat patients for drug dependence. There are separate recordkeeping and security requirements for Narcotic Treatment Programs. The CFR requirements for narcotic treatment programs include:

- *Official Order Forms* (DEA Form-222) are required for all Schedule II narcotic transactions between a narcotic treatment program and any registrant, including a manufacturer, distributor, practitioner or another narcotic treatment program.
- A narcotic treatment program registered with DEA can handle only the narcotic substances applied for on the DEA Form-363 (New Application Registration, see Appendix K) and that are approved for use in maintenance or detoxification.
- Controlled substances for treatment of conditions other than narcotic addiction cannot be administered, dispensed or stored on the premises of a narcotic treatment program unless a physician has a valid practitioner registration at the program location.

Use of Methadone Outside a Narcotic Treatment Program

1. A practitioner may prescribe methadone or any other narcotic to a narcotic addict for analgesic purposes. However, a practitioner may not prescribe methadone or any other narcotic medication solely for the treatment of a patient's narcotic addiction. The individual must receive the narcotics at a registered narcotic treatment program. In this case, the narcotics can be dispensed or administered but not prescribed. (The regulations do not prohibit the prescribing, administering or dispensing of methadone for analgesic purposes for medical conditions other than addiction.)
2. A practitioner who is not part of a narcotic treatment program may administer narcotic substances to an addicted individual to relieve that individual's acute withdrawal symptoms while the practitioner makes arrangements to refer the individual to a narcotic treatment program. Not more than one day's medication may be administered at one time. This treatment cannot last more than three days and may not be renewed or extended.
3. A hospital that has no narcotic treatment program on the premises may administer narcotics to a drug dependent individual for either detoxification or maintenance purposes, if the individual is being treated for a medical condition other than narcotic addiction.

If you have questions regarding any part of the Narcotic Addict Treatment Act of 1974 or its regulations, contact the nearest DEA Diversion Field Office (see Appendix T).

Narcotics for Patients with Terminal Illnesses or Intractable Pain

Controlled substances, particularly narcotic analgesics, may be used in the treatment of pain experienced by a patient with a terminal illness or intractable pain. These drugs have legitimate uses and a pharmacist should not hesitate to dispense them when a prescription indicates they are for a legitimate medical purpose. (The CSA requires that a controlled substance prescription must be issued for a legitimate medical purpose by a practitioner acting in the course of professional practice. [Title 21 CFR 1306.04]. The CSA does not define "legitimate medical practice" nor does it set forth "standards of medical practice.")

A pharmacist need not fear DEA action if he/she dispenses controlled substances in good faith pursuant to a prescription issued for a legitimate medical purpose. It is the position of the DEA that controlled substances should be prescribed and dispensed when there is a legitimate medical need.

Inappropriate prescribing and dispensing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek these drugs for purposes other than legitimate medical use. However, pharmacists should recognize that drug tolerance and physical dependence may develop as a consequence of the patient's sustained use of opioid analgesics for the legitimate treatment of chronic pain. It is also important to understand that the quantity of drugs prescribed and frequency of prescriptions filled alone are not indicators of fraud or improper prescribing.

A pharmacist's professional judgement is the first step in determining the appropriate course of action when the pharmacist is presented with a prescription that appears questionable. The pharmacist's judgement, in consultation with the prescriber, is the best way to verify that the prescription is for a legitimate medical need. The pharmacist, in cooperation with the prescribing practitioner, has a responsibility to continue to monitor the patient receiving the controlled substance in order to prevent abuse or diversion.

Other Controlled Substance Regulations

Controlled Substances for Medical Missions and Humanitarian Charitable Solicitations

DEA assists organizations and practitioners who provide charitable medical, dental and veterinary treatment in foreign countries. In order for practitioners to hand carry controlled substances overseas, they must obtain approval from DEA and the appropriate authority in the foreign country. Practitioners interested in cooperating with such medical missions should contact their local DEA Diversion Field Office (see Appendix T) or the International Drug Unit, DEA, Office of Diversion Control, Washington, D.C. 20537, for instructions. Allow at least 30 days to obtain the necessary approvals.

If a pharmacy is asked to donate controlled substances to charitable organizations, contact your state controlled substance agency to determine if you have state authority to do so and your local DEA Diversion Field Office for further guidance. The shipment of controlled substances abroad is considered to be an export, which may only be done by a DEA registered exporter.

Controlled Substance Distribution by a Pharmacy

A pharmacy registered to dispense controlled substances may distribute such substances (without being registered as a distributor) to another pharmacy or to a practitioner to dispense, provided that the following conditions are met:

1. The pharmacy or practitioner is registered under the CSA to dispense controlled substances.

2. The pharmacy records that it distributed the controlled substances, and the recipient pharmacy or practitioner records that they received the controlled substances.
3. If a Schedule II controlled substance is distributed, the transfer must be documented on an Official Order Form (DEA Form-222). The distributing pharmacy must record the following information on an Official Order Form:
 - The name of the substance, the dosage form, and the quantity.
 - The name, address and DEA registration number of the pharmacy or practitioner to whom it is distributed.
4. **Five Percent Rule.** The total number of dosage units of controlled substances distributed by a pharmacy may not exceed five percent of all controlled substances dispensed by the pharmacy during a calendar year. If at any time the controlled substances distributed exceeds five percent, the pharmacy is also required to register as a distributor.

U.S. Postal Service Mailing Requirements for Controlled Substances

U.S. Postal Service regulations permit mailing any controlled substances, provided that they are not outwardly dangerous or of their own force could cause injury to a person's life or health, if the following preparation and packaging standards are met:

1. The inner container of any parcel containing controlled substances is marked and sealed under the provisions of the Controlled Substances Act and its implementing regulations, and placed in a plain outer container or securely wrapped in plain paper.

2. If the controlled substances consist of prescription medicines, the inner container is also labeled to show the name and address of the pharmacy, practitioner or other person dispensing the prescription.
3. The outside wrapper or container is free of markings that would indicate the nature of the contents.

Chemical Requirements: Comprehensive Methamphetamine Control Act of 1996

Retail pharmacies that are registered to handle controlled substances need not obtain a separate DEA chemical registration for retail distribution of pseudoephedrine, phenylpropanolamine (PPA), combination ephedrine and single-entity ephedrine drug products. However, if you are going to handle these products containing List I chemicals, you must comply with the recordkeeping and reporting requirements of the Comprehensive Methamphetamine Control Act of 1996 (MCA). Recordkeeping includes documentation of both receipts and sales of threshold amounts of List I chemical drug products. The MCA requirements also include reporting mail order transactions, such as drugs delivered by the U.S. Postal Service or any private or commercial carrier.

It is unlikely that pharmacies will engage in transactions involving List II Chemicals (see Appendix C, **List II Chemicals with Threshold Amounts**) in quantities that meet or exceed thresholds for recordkeeping and reporting requirements, therefore this manual summarizes only the requirements for List I chemicals. If you engage in List II chemical transactions which meet or exceed threshold limits in Appendix C, you should contact your local DEA Diversion Field Office for further information.

Summary of MCA's Major Provisions which Concern Pharmacists (including amendments by the Methamphetamine Anti-Proliferation Act (MAPA) of 2000)

1. The MCA defines a retail distributor as a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor of pseudoephedrine, phenylpropanolamine (PPA), and combination ephedrine drug products are limited almost exclusively to sales for personal use, both in number and volume of sales, either to walk-in customers or in face-to-face transactions by direct sales. Personal use is defined as sub-threshold sales in a single transaction to an individual for legitimate medical use. All distribution of single entity ephedrine are subject to the registration requirement.
2. Threshold quantities have been set for sales of listed chemicals contained in drug products. If the pharmacy engages in any above-threshold retail transactions of pseudoephedrine (9 grams), PPA (9 grams), combination ephedrine (24 grams) and single-entity ephedrine drug products (all transactions are regulated), you must maintain a record of these transactions for two years. You must also obtain proof of identity from customers and report suspicious above-threshold retail transactions immediately to DEA. (See Appendix A, **Number of Tablets that Equal a Threshold (Regulated) Transaction for Dosage Units of Marketed Products.**)
3. While a single transaction of pseudoephedrine and PPA drug products in blister packs (defined as ordinary over-the-counter pseudoephedrine and phenylpropanolamine drug products) is exempt from being considered a "regulated transaction," the definition of a retail distributor requires that the sales of regulated pseudoephedrine and

PPA products regardless of packaging- are almost exclusively to be below the 9 gram threshold (in packages of not more than 3 grams) to individuals for legitimate medical use. An occasional above-threshold sale of blister packs is not subject to the recordkeeping requirement.

4. All **transactions** of ephedrine, pseudoephedrine and PPA to non-regulated parties by postal, private or commercial carrier **must be reported to DEA on a monthly basis**, regardless of size of the transaction **with the following exceptions**

Exemptions:

-Distributions of drug products by retail distributors that may not include face-to-face transactions to the extent that such distributions are consistent with the activities authorized for a retail distributor as specified in the definition of a retail distributor (See number 1.)

-Distributions of drug products pursuant to valid prescriptions.

-Distributions of drug products to a long term care facility for dispensing to or for use by a resident of that facility.

-Distributions of sample packages of drug products when such packages contain not more than 2 solid dosage units or the equivalent of 2 dosage units in liquid form, not to exceed 10 liters of liquid per package, and not more than one package is distributed to an individual or residential address in any 30-day period.

The data required for such reports must include:

- a. Name of the purchaser.
- b. Quantity and form of the ephedrine, pseudoephedrine, or PPA purchased.
- c. The address to which such drug products were sent.
- d. Date of each transaction.

- e. Other items of information which may be required by regulation.

5. Retail distributors of List I chemical drug products who do not have a DEA registration may make infrequent and small quantity sales of pseudoephedrine, PPA or combination ephedrine to another store, if that store is in short supply of these products. However, retail distributors should be **extremely cautious** with such transactions, since they are required to limit their sales of these products "almost exclusively, both in number of sales and volume of sales" to "walk-in customers or in face-to-face transactions by direct sales."

- a. Therefore, depending upon a retailer's volume of sales, a single large quantity sale to another store could mean the retailer no longer satisfies the definition of "retail distributor," and would be required to register as a distributor of List chemicals.

- b. Even if a retailer is able to complete this transaction without affecting its status as a retail distributor, a record of the transaction must be maintained if it meets the 9 gram threshold for pseudoephedrine and PPA or the 24 gram threshold for combination ephedrine drug products.

6. A person is subject to criminal prosecution who distributes a listed chemical, any other chemical, chemical product or chemical equipment knowing, or having reasonable cause to believe, that such chemical, product or equipment will be used in the illegal manufacture of a controlled substance. (See Appendix A, **Number of Tablets that Equal a Threshold (Regulated) Transaction for Dosage Units of Marketed Products**; See Appendix B, **List I Chemicals with Threshold Amounts**, and see Appendix C, **List II Chemicals with Threshold Amounts**.)

Regulated Chemicals

Most of the chemicals regulated under the CSA will not be encountered in a pharmacy setting or in quantities subject to recordkeeping and reporting requirements. List I chemicals are mostly precursors used for the manufacture of controlled substances and actually become part of the final drug molecule. Examples include anthranilic acid, ephedrine, ergotamine, norpseudoephedrine, phenylacetic acid, PPA and pseudoephedrine. (See Appendix A, **Number of Tablets that Equal a Threshold (Regulated) Transaction for Dosage Units of Marketed Products**, and Appendix B, **List I Chemicals with Threshold Amounts**.)

List II chemicals are mostly solvents and reagents that can be used in the manufacture of controlled substances. Examples include ethyl ether, potassium permanganate, acetone and toluene. (Appendix C, **List II Chemicals with Threshold Amounts**.)

Records for List I Chemicals

Records of regulated transactions must be maintained separately or distinguished in some manner from records for controlled substances and records for List I chemicals. All such records must be maintained for a period of two years. It is suggested that the required records be maintained in a bound log book like that used to record the dispensing of Schedule V controlled substances. Some states have passed legislation or regulations requiring that certain List I chemicals be dispensed pursuant only to a prescription. In those jurisdictions, the prescription will suffice as the dispensing record. Inventories of List I chemicals are **not** required.

Proof of Identity Requirement for Purchasers of List I Chemicals

Before List I chemicals can be dispensed, pharmacists must obtain proof of identity from cash purchasers or individuals buying threshold quantities of List I chemicals. Proof of identity must be in the form of a driver's license, one other form of identification and the purchaser's signature. If the product is dispensed pursuant to a prescription, regular prescription records will suffice.

Excessive or Unusual Purchases of List I Chemicals (Suspicious Orders)

Drug products containing ephedrine, pseudoephedrine or PPA are usually sold to individuals in quantities for personal use. Combination drug products packaged for the retail market are the precursor material found at nearly 95% of the methamphetamine laboratories seized by DEA. This fact shows that the pharmacy industry has an important role in preventing diversion of legitimate products to methamphetamine production. Pharmacists should be alert for persons who want to buy a large quantity of over-the-counter drug products containing these chemicals since they can be used in the clandestine manufacture of controlled substances. Pharmacists should also be aware that persons seeking large quantities of List I chemical products from pharmacies frequently claim they will export the products.

Any regulated transaction for a List I chemical involving an extraordinarily large quantity, an uncommon method of payment or delivery, or any other circumstance that may lead the pharmacist to believe that the listed chemical will be used in violation of the law, must be reported to the local DEA Diversion Field Office (see Appendix T). Each report shall be made orally at the earliest practicable opportunity after the pharmacist becomes aware of the circumstances involved and as much in advance of the transaction as possible. Within 15 days a written report of the transaction should be forwarded to your local DEA Diversion Field Office and must include the following information:

1. The name, address, and, if required, DEA registration number of each party to the regulated transaction.

2. The date of the regulated transaction.
3. The name, quantity and form of packaging of the listed chemical or a description of the tableting machine or encapsulating machine (including make, model, and serial number).
4. The method of transfer (company truck, picked up by customer, etc.).
5. The type of identification used by the purchaser and any unique number on that identification.

List I Chemical Security

Single-entity ephedrine products must be stocked behind a counter where only employees have access. However, there is no such requirement for pseudoephedrine or PPA drug products.

Appendix A

Number of Tablets that Equal a Threshold (Regulated) Transaction for Dosage Units of Marketed Products

Combination Ephedrine		
Threshold (in base)	#25 mg Tablets HCL	#25 mg Tablets Sulfate
Wholesale: 1,000 grams	48,827	51,872
Retail: 24 grams	1,172	1,245

Pseudoephedrine						
Threshold (in base)	#120 mg Tabs HCL	#120 mg Tabs Sulfate	#60 mg Tabs HCL	#60 mg Tabs Sulfate	#30 mg Tabs HCL	#30 mg Tabs Sulfate
Wholesale: 1,000 grams	10,173	10,807	20,345	21,614	40,689	43,227
Retail: 9gms /transaction*	92	98	184	195	367	390
Retail: 3gms /package*	31	33	62	65	123	130

Phenylpropanolamine				
Threshold (in base)	#75 mg Tabs HCL	#25 mg Tabs HCL	#12.5 mg Tabs HCL	#6.25 mg Tabs HCL
Wholesale: 2,500 grams	41,371	124,113	248,226	496,452
Retail: 9gms /transaction*	149	447	894	1,788
Retail: 3gms /package*	50	149	298	596

* Thresholds of 9 grams per single transaction and more than 3 grams per package are mandated by the Methamphetamine Anti-Proliferation Act (Children's Health Act of 2000).

Appendix B

List I Chemicals With Domestic Threshold Amounts

List 1 Chemical	Threshold (by base weight)
N-Acetylanthranilic acid and its salts and esters	40 kg
Anthranilic acid and its salts and esters	30 kg
Benzaldehyde	4 kg
Benzyl cyanide	1 kg
Ephedrine and its salts, optical isomers, and salts of Optical isomers	0 kg
Ergonovine and its salts	10 gm
Ergotamine and its salts	20 gm
Ethylamine and its salts	1 kg
Gamma-butyrolactone (GBL)	0 kg ¹
Hydriodic acid (57%)	1.7 kg ²
Hypophosphorus acid and its salts	0 kg ³
Isosafrole	4kg
Methylamine and its salts	1kg
3, 4 Methyleneedioxyphenyl – 2 propanone	4 kg
N- Methylephedrine and its salts, optical isomers, And salts of optical isomers	1 kg
N-Methylpseudoephedrine and its salts, optical isomers, and salts of optical isomers	1 kg
Nitroethane	2.5 kg
Norpseudoephedrine and its salts, optical isomers, and salts of optical isomers	2.5 kg
Phenylacetic acid and its salts and esters	1 kg
Phenylpropanolamine and its salts, optical isomers, And salts of optical isomers	2.5 kg
Phosphorus red,white	0 kg ³
Piperidine and its salts	500 gm
Piperonal	4 kg
Propionic anhydride	1 gm
Pseudoephedrine and its salts, optical isomers, and salts of optical isomers	1 kg
Safrole (includes Safrole-rich essential oils, such as sassafras Oil and camphor oil 1070)	4 kg

¹ Until a permanent threshold is established in the Federal Register, **all** transactions are regulated.

² One liter by volume.

³ See 65 FR 57577 for transactions that are exempt on an interim basis.

Appendix C

List II Chemicals With Domestic Threshold Amounts

List II Chemical	Threshold	
	Volume	Weight
Acetic anhydride	250 gallons	1023 kgs
Acetone	50 gallons ⁴	150 kgs ¹
Benzyl chloride	Not applicable	1 kg
Ethyl ether	50 gallons	135.8 kgs
Hydrochloric Acid	Not regulated	Not regulated
Anhydrous hydrogen chloride	Not applicable	0.0 kgs
Iodine	Not applicable	0.4 kgs
Potassium Permanganate	Not applicable	55 kgs
Methyl ethyl ketone (2-Butane)	50 gallons ¹	145 kgs ¹
Methyl isobutyl ketone	Not regulated	Not regulated
Sulfuric acid	Not regulated	Not regulated
Toluene	50 gallons ¹	159 kgs ¹

⁴ The cumulative threshold is **not** applicable to domestic sales of these chemicals.

Appendix D

Summary of Controlled Substances Act Requirements⁵

Requirement	Schedule II	Schedule III & IV	Schedule V
Registration	Required	Required	Required
Receiving Records	Order forms (DEA Form-222)	Invoices, Readily Retrievable	Invoices, Readily Retrievable
Prescriptions	Signed Prescription ⁶	Written, Oral, or Fax	Written, Oral, Fax, OTC ⁷
Refills	No	5 in 6 months	Only as authorized if a prescription is issued
Maintenance of Prescriptions	Separate or with readily retrievable Schedules III-v	Separate or readily retrievable;	Separate or readily retrievable; Bound dispensing log book
Distribution between Registrants	Order forms (DEA Form-222)	Invoices	Invoices
Security	Locked cabinet, Dispersed, Other secure storage	Locked cabinet, Dispersed, Other secure storage	Locked cabinet, Dispersed, Other secure storage
Theft or Significant Loss	Report immediately before filing DEA Form 106	Report immediately before filing DEA Form 106	Report immediately before filing DEA Form 106

⁵ All records must be maintained for two years, unless state requires a longer period

⁶ Emergency Prescriptions require signed follow-up prescription. Exceptions; Fax prescription serves as original prescription for home infusion IV, long term care facility, and hospice.

⁷ Where authorized by state controlled substances authority.

Appendix E

DEA Form-224

Application for new registration under Controlled Substances Act of 1970

READ INSTRUCTIONS BEFORE COMPLETING
USE BLACK INK

**APPLICATION FOR REGISTRATION
UNDER CONTROLLED SUBSTANCES ACT OF 1970**

APPROVED OMB NO. 1117-0014
FORM DEA-224 (11-85)
Previous editions are obsolete

NAME - APPLICANT OR BUSINESS NAME

DATE

NO REGISTRATION WILL BE ISSUED UNLESS A completed application form has been received (21 CFR 1301.15)

The Data Collection Improvement Act of 1996 (PL 104-281) requires that you provide your Taxpayer Identification Number (and/or Social Security Number) to DEA. This number is required for data collection on procedures should your tax status ever change.

REGISTRATION CLASSIFICATION

1. BUSINESS ACTIVITY (SEE INSTRUCTIONS)

A. ☐ RETAIL PHARMACY B. ☐ HOSPITAL/CLINIC C. ☐ PRACTITIONER (Specify professional degree)

D. ☐ TEACHING INSTITUTION (Specify institution)

E. ☐ INDIVIDUAL PRACTITIONER (Specify professional degree and specialty)

2. DRUG SCHEDULES (If you select more than one, check all that apply)

SCHEDULE I ☐ SCHEDULE II ☐ SCHEDULE III ☐ SCHEDULE IV ☐ SCHEDULE V ☐

3. ALL APPLICANTS MUST ANSWER THE FOLLOWING:

(a) Are you currently authorized to prescribe, dispense, dispense, conduct research, or otherwise handle the controlled substances in the schedule for which you are applying under the laws of the state or jurisdiction in which you are operating or propose to operate? When transferring your registration to a new state, you must submit a copy of your current certificate for the new state.

YES - STATE LICENSE NO.

YES - STATE CONTROLLED SUBSTANCE NO.

If you have answered "yes" to the following question(s) on previous applications, you must continue to answer "yes" and provide a statement of explanation.

(b) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law? YES NO

(c) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(d) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(e) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(f) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(g) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(h) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(i) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(j) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(k) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(l) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(m) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(n) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(o) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(p) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(q) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(r) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(s) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(t) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(u) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(v) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(w) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(x) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(y) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(z) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

ATTENTION - FEE IS \$390 FOR 3 YRS

Note: This sample form may not be used in place of an actual application.

Appendix F

DEA Form-224a – Renewal Application for DEA registration under Narcotic Addict Treatment Act of 1974

READ INSTRUCTIONS BEFORE COMPLETING
USE BLACK INK

**RENEWAL
APPLICATION FOR DEA REGISTRATION
UNDER CONTROLLED SUBSTANCES ACT OF 1970**

APPROVED OMB NO. 1117-0014
FORM DEA-224a (8-02)
Previous editions are obsolete

No registration will be issued unless a completed application form has been received (21 CFR 1301.15)

1. DRUG SCHEDULES (SEE INSTRUCTIONS)

SCHEDULE I ☐ SCHEDULE II ☐ SCHEDULE III ☐ SCHEDULE IV ☐ SCHEDULE V ☐

2. INDICATE HERE IF YOU REQUIRE ORDER FORM BOOKS.

YES - STATE LICENSE NO.

YES - STATE CONTROLLED SUBSTANCE NO.

3. ALL APPLICANTS MUST ANSWER THE FOLLOWING:

(a) Are you currently authorized to prescribe, dispense, dispense, conduct research, or otherwise handle the controlled substances in the schedule for which you are applying under the laws of the state or jurisdiction in which you are operating or propose to operate? When transferring your registration to a new state, you must submit a copy of your current certificate for the new state.

YES - STATE LICENSE NO.

YES - STATE CONTROLLED SUBSTANCE NO.

If you have answered "yes" to the following question(s) on previous applications, you must continue to answer "yes" and provide a statement of explanation.

(b) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law? YES NO

(c) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(d) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(e) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(f) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(g) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(h) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(i) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(j) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(k) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(l) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(m) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(n) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(o) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(p) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(q) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(r) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(s) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(t) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(u) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(v) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(w) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(x) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(y) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

(z) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law, or placed on probation? YES NO

4. EXPLANATION FOR ANSWERING "YES" TO ITEM(S) 3(b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), (p), (q), (r), (s), (t), (u), (v), (w), (x), (y), (z).

Applicants who have answered "yes" to item(s) 3(b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), (p), (q), (r), (s), (t), (u), (v), (w), (x), (y), (z) are required to submit a statement explaining such response(s). The space provided below should be used for this purpose. If additional space is needed, use a separate sheet and attach with application.

DEA REGISTRATION NUMBER

YOUR CURRENT REGISTRATION EXPIRES ON

ATTENTION

Note: This sample form may not be used in place of an actual application

Appendix G

DEA Form- 224b – Sample of Retail pharmacy renewal affidavit for chain renewal

DEA Form - 224b (5/95) **Affidavit for Chain Renewal** **DEA Retail Pharmacy Registrations** OMB No. 1517-0014
Filing notification to currently approved information collection.

No registration may be issued unless a completed application form has been received (21 CFR 1301.13). This affidavit is provided in lieu of a separate DEA application form for each registration on the attached list.

I hereby certify that the answers to the questions below pertain to each of the registrations on the attached list in the category of retail pharmacy for the Corporation.

(a) Are the listed locations currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle controlled substances in the schedules for which they currently are authorized on their DEA registration under the laws of the State or jurisdiction in which they are operating? ☐ Yes ☐ No

(b) Has the applicant ever been convicted of a crime in connection with controlled substances under State or Federal law, or ever surrendered or had a State professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending against the applicant? ☐ Yes ☐ No

(c) If the applicant is a corporation (other than a corporation whose stock is owned and traded by the public), association, partnership, or pharmacy, has any officer, partner, stockholder or proprietor been convicted of a crime in connection with controlled substances under State or Federal law, or ever surrendered or had a Federal controlled substance registration revoked, suspended, restricted or denied, or ever had a State professional license or controlled substance registration revoked, suspended, denied, restricted or placed on probation, or is any such action pending against the applicant? ☐ Yes ☐ No

IF THE ANSWER TO QUESTIONS (b) or (c) IS YES FOR ANY LOCATION, INCLUDE A STATEMENT EXPLAINING SUCH RESPONSE(S).

Signature of authorized individual (must be an original ink signature) _____ Date _____

Title of the person signing on behalf of the applicant _____ Applicant's Business Phone Number _____

The application fee for the applicants on the attached is \$ _____.
Fees are not refundable.

Note: This sample form may not be used in place of an actual application.

Appendix H

DEA Form 222 – U.S. Official Order Form Schedules I & II

See Reverse of PURCHASER'S Copy for Instructions. No order may be issued for Schedules I and II substances without a completed application form (see reverse of this form). OMB APPROVAL No. 1517-0014

TO: Name of Supplier _____ STREET ADDRESS _____

CITY and STATE _____ DATE _____

TO BE FILLED IN BY PURCHASER

No.	No. of Packages	Size or Potency	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

TO BE FILLED IN BY SUPPLIER

SUPPLIER'S DEA REGISTRATION NO. _____

LAST LINE COMPLETED (MUST BE IN OR LESS)

Signature of purchaser (or attorney or agent) _____

Name and Address of Registrant _____

DEA Registration No. _____

Schedule _____

Registered at _____

No. of this Order Form _____

DEA Form 222 (04-1990) **U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II** **DRUG ENFORCEMENT ADMINISTRATION** **SUPPLIER'S Copy 1** **55690024**

Note: This sample form may not be used in place of an actual application.

Appendix I

DEA Form 41 – Registrants Inventory of Drugs Surrendered

OMB Approval No. 1517-0007 U. S. Department of Justice - Drug Enforcement Administration REGISTRANTS INVENTORY OF DRUGS SURRENDERED		PACKAGE NO.				
The following schedule is an inventory of controlled substances which is hereby surrendered to you for proper disposition, per your approval.						
FROM: (Include Name, Street, City, State and ZIP Code in space provided below)						
Signature of applicant or authorized agent		REGISTRANT'S DEA NUMBER				
REGISTRANT'S TELEPHONE NUMBER		NOTE: REGISTERED MAIL (Return Receipt Requested) IS REQUIRED FOR SHIPMENTS OF DRUGS VIA U. S. POSTAL SERVICE.				
NAME OF DRUG OR PREPARATION Registrants will fill in Columns 1, 2, 3, and 4 ONLY.	Number of Containers	CONTENTS (Number of grams, tablets, capsules, or other units per container)	Controlled Substances Code (Each Unit)	FOR DEA USE ONLY		
				DISPOSITION	QUANTITY	
					GMS.	MGS.
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						

FORM DEA-41 (9-02) Previous editions are obsolete.
Electronic Form Version Designed in Jefferson 5.2 Version

See instructions on reverse (page 2) of form.

Note: This sample form may not be used in place of an actual application.

Appendix J

DEA Form 106 – Report of Theft or Loss of Controlled Substances

U. S. Department of Justice Drug Enforcement Administration	
REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES	
Federal Regulations require registrants to submit a detailed report of any theft or loss of Controlled Substances to the Drug Enforcement Administration. Complete the front and back of this form in duplicate. Forward the original and duplicate copies to the nearest DEA Office. Retain the triplicate copy for your records. Some states may also require a copy of this report.	
1. Name and Address of Registrant (Include ZIP Code)	2. Phone No. (Include Area Code)
3. DEA Registration Number	4. Date of Theft or Loss
5. Principal Business of Registrant (Check one)	6. Name and Telephone Number of Police Department (Include Area Code)
<input type="checkbox"/> 1 Pharmacy <input type="checkbox"/> 2 Dispensary <input type="checkbox"/> 3 Manufacturer <input type="checkbox"/> 4 Hospital/Clinic	<input type="checkbox"/> 5 Distributor <input type="checkbox"/> 6 Medication Program <input type="checkbox"/> 7 Other (Specify)
7. County in which Registrant is located	8. Was theft reported to Police?
	<input type="checkbox"/> Yes <input type="checkbox"/> No
9. Number of Theft or Losses Registrant has experienced in the past 24 months	10. Type of Theft or Loss (Check one and complete items below as appropriate)
	<input type="checkbox"/> 1 Night break-in <input type="checkbox"/> 2 Armed robbery <input type="checkbox"/> 3 Employee pilferage <input type="checkbox"/> 4 Customer theft
11. If Armed Robbery, was anyone:	12. Purchase value for registrant of Controlled Substances taken?
Killed? <input type="checkbox"/> No <input type="checkbox"/> Yes (How many) _____ Injured? <input type="checkbox"/> No <input type="checkbox"/> Yes (How many) _____	\$ _____
13. Where any pharmaceuticals or merchandise taken?	14. If LOST IN TRANSIT, (COMPLETE THIS SECTION)
<input type="checkbox"/> No <input type="checkbox"/> Yes (Est. Value) \$ _____	
A. Name of Carrier/Carrier	B. Name of Consignee
C. Consignee's DEA Registration Number	
D. Was the carton received by the customer?	E. If received, did it appear to be tampered with?
<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
F. Have you experienced losses in transit from this same carrier in the past?	
<input type="checkbox"/> No <input type="checkbox"/> Yes (How many) _____	
15. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?	
16. If Official Controlled Substances Order Forms (DEA-202) were stolen, give numbers.	
17. What security measures have been taken to prevent future thefts or losses?	
PRIVACY ACT INFORMATION AUTHORITY: Section 501 of the Controlled Substances Act of 1970 (PL 91-613). PURPOSE: Report theft or loss of Controlled Substances. ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosure of information from this system are made to the following categories of users for the purposes stated: A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes. B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes. EFFECT: Failure to report theft or loss of controlled substances may result in penalties under Section 400 and 405 of the Controlled Substances Act.	
FORM DEA-106 (11-00) Previous editions obsolete. Electronic Form Version Designed in Jefferson 5.2 Version	

CONTINUE ON REVERSE

Note: This sample form may not be used in place of an actual application.

What is the pharmacist expected to do when presented with a prescription that raises questions? Although a pharmacist may be reluctant to "get involved," there really is no choice. The pharmacist is involved because their professional responsibilities makes him or her subject to the requirements of the CSA. If you find one or two prescriptions which appear to be irregular, the best remedy may be to call the prescribing physician about your concern. Often, a friendly bit of advice from a fellow professional may be all that is needed to correct an apparent irregularity.

However, where there appears to be a pattern of prescription abuses, the pharmacist's refusing to dispense certain prescriptions may not be enough. Abusers will simply go elsewhere, possibly to another pharmacist with whom the prescriber has an understanding. In such cases, the pharmacist should contact the State Board of Pharmacy or the local DEA Diversion Field Office. Both DEA and State authorities consider retail-level diversion priority problems. Your information will be handled confidentially and promptly. DEA cannot, however, get to the source of the diversion without your cooperation.

Appendix O

Pharmacist's Guide to Prescription Fraud

The purpose of this guide is to ensure that controlled substances continue to be available for legitimate medical and scientific purposes while preventing their diversion into the illicit market. It is not the intent of this publication to discourage or prohibit the use of controlled substances where medically indicated. DEA supports the 1998 "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain" prepared by the Federation of State Medical Boards of the United States, Inc. DEA believes that the "Model Guidelines" will protect legitimate medical uses of controlled substances while preventing drug diversion.

Nothing in this guide should be construed as authorizing or permitting any person to conduct any act that is not authorized or permitted under Federal or state laws.

Your Responsibilities

The abuse of prescription drugs—especially controlled substances—is a serious social and health problem in the United States today. As a healthcare professional, you share responsibility for solving the prescription drug abuse and diversion problem.

You have a legal responsibility to acquaint yourself with the state and Federal requirements for dispensing controlled substances. You also have a legal and ethical responsibility to uphold these laws and to help protect society from drug abuse.

You have a personal responsibility to protect your practice from becoming an easy target for drug diversion. You must become aware of the potential situations where drug diversion can occur and safeguards that can be enacted to prevent this diversion.

- The dispensing pharmacist must maintain a constant vigilance against forged or altered prescriptions. The law holds the pharmacist responsible for knowingly dispensing a prescription that was not issued in the usual course of professional treatment.

This guide will help you meet these responsibilities.

Types of Fraudulent Prescriptions

The practiced forger of prescriptions is usually very adept at the job. The forger knows what information is needed on the prescription to make it appear authentic. Pharmacists should be aware of the various kinds of forged prescriptions that may be presented for dispensing.

Some patients, in an effort to obtain additional amounts of legitimately prescribed drugs, alter the physician's prescription. They will also have prescription pads printed using a legitimate doctor's name, but with a different call back number that is answered by an accomplice to verify the prescription. Also, drug seeking individuals will call in their own prescriptions and give their own telephone number as a call back confirmation.

Legitimate prescription pads are stolen from physicians' offices and hospitals and prescriptions are written using fictitious patients names and addresses. In addition, individuals will go to emergency rooms complaining of pain in the hopes of receiving a controlled substance prescription. The prescription can then be altered or copied to be used again. Computers are often used to create prescriptions for nonexistent doctors or to copy legitimate doctors' prescriptions.

Note: The quantity of drugs prescribed and frequency of prescriptions filled are not alone indications of fraud or improper prescribing especially if the patient is being treated with opioids for pain management. Pharmacists should also recognize that drug tolerance and physical dependence may develop as a consequence of the patient's sustained use of opioid analgesics for the legitimate treatment of chronic pain.

The following criteria may indicate that a prescription was not issued for a legitimate medical purpose.

- The prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in your area.
- The patient appears to be returning too frequently. Prescription which should last for a month in legitimate use, is being refilled on a biweekly, weekly or even a daily basis.
- The prescriber writes prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time. Drug abusers often request prescriptions for "uppers and downers" at the same time.
- Patient appears presenting prescriptions written in the names of other people.
- A number of people appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician.
- Numerous "strangers," people who are not regular patrons or residents of your community, suddenly show up with prescriptions from the same physician.

Characteristics of Forged Prescriptions

1. Prescription looks "too good"; the prescriber's handwriting is too legible;
2. Quantities, directions or dosages differ from usual medical usage;
3. Prescription does not comply with the acceptable standard abbreviations or appear to be textbook presentations;
4. Prescription appears to be photocopied;
5. Directions written in full with no abbreviations;

6. Prescription written in different-color inks or written in different handwriting.
7. Apparent erasure marks.

Prevention Techniques

- Know the prescriber and his/her signature;
- Know the prescriber's DEA registration number;
- Know the patient;
- Check the date on the prescription order. Has it been presented to you in a reasonable length of time since the prescriber wrote it?

When there is a question about **any** aspect of the prescription order, call the prescriber for verification or clarification. Should there be a discrepancy, the patient must have a plausible reason **before** the prescription medication is dispensed.

Any time you are in doubt, require proper identification. Although this procedure isn't foolproof (identification papers can also be stolen/forged), it does increase the drug abuser's risk.

If you believe that you have a forged, altered, or bogus prescription--don't dispense it--call your local police.

If you believe that you have discovered a pattern of prescription abuses, contact your State Board of Pharmacy or your local DEA office. Both DEA and state authorities consider retail-level diversion a priority issue.

Proper Controls

Dispensing procedures, without control and professional caution, are an invitation to the drug abuser. Proper controls against bogus prescriptions can best be accomplished by following common sense, sound professional practice, and proper dispensing procedures and controls.

Have your pharmacy staff help protect your practice from becoming a source of prescription drug diversion. Become familiar with which drugs are popular for abuse and resale on the streets in your area. Drug abuse prevention must be an ongoing staff activity.

Encourage local pharmacists and physicians to develop a network, or at least a working relationship, which promotes teamwork and camaraderie. Discuss abuse problems with other pharmacists and physicians in the community. Most drug abusers seek out areas where communication and cooperation between health professionals are minimal because it makes their work so much easier.

Appendix P

Affidavit for a New Pharmacy¹

I, _____, the
 _____ (Title of officer, official, partner, or other
 position) of _____ (Corporation,
 partnership, or sole proprietor), doing business as
 _____ (Store name)
 at _____ (Number and Street),
 _____ (City) _____ (State)
 _____ (Zip Code), hereby certify that said store was
 issued a pharmacy permit No. _____ by the
 _____ (Board of Pharmacy or Licensing
 Agency) of the State of _____ on
 _____ (Date).

This statement is submitted in order to obtain a Drug Enforcement Administration registration number. I understand that if any information is false, the Administration may immediately suspend the registration for this store and commence proceedings to revoke under 21 U.S.C. 824(a) because of the danger to public health and safety. I further understand that any false information contained in this affidavit may subject me personally and the above-named corporation/partnership/business to prosecution under 21 U.S.C. 843, the penalties for conviction of which include imprisonment for up to four (4) years, a fine of not more than \$30,000.00 or both.

 Signature (Person who signs Application for Registration)

State of _____

County of _____

Subscribed to and sworn before me this _____ day of
 _____, 19____.

 Notary Public

¹ 21 CFR, Section 1301.17(a)

Appendix Q

Affidavit for Transfer of a Pharmacy¹

I, _____, the
 _____ (Title of officer, official, partner, or other
 position) of _____ (Corporation,
 partnership, or sole proprietor), doing business as
 _____ (Store name)
 hereby certify:

(1) That said company was issued a pharmacy permit No.
 _____ by the _____
 (Board of Pharmacy or Licensing Agency) of the State of _____
 and a DEA Registration Number
 _____ for a pharmacy located at
 _____ (Number and Street),
 _____ (City)
 _____ (State) _____ (Zip
 Code),; and

(2) That said company is acquiring the pharmacy business of
 _____ (Name of Seller)
 doing business as _____ with DEA
 Registration Number _____ on or
 about _____ (Date of Transfer) and that said
 company has applied (or will apply on _____
 (Date) for a pharmacy permit from the Board of Pharmacy (or Licensing
 Agency) of the State of _____ to do business as
 _____ (Store name) at
 _____ (Number and Street)
 _____ (City) _____ (State)
 _____ (Zip Code).

**This statement is submitted in order to obtain a Drug
 Enforcement Administration registration number.**

I understand that if a DEA registration number is issued, the
 pharmacy may acquire controlled substances but may not dispense them
 until a pharmacy permit or license is issued by the State board of
 pharmacy or licensing agency.

¹ 21 CFR, Section 1301.17(a)

I understand that if any information is false, the Administration
 may immediately suspend the registration for this store and commence
 proceedings to revoke under 21 U.S.C. 824(a) because of the danger to
 public health and safety. I further understand that any false information
 contained in this affidavit may subject me personally and the above-
 named corporation/partnership/business to prosecution under 21 U.S.C.
 843, the penalties for conviction of which include imprisonment for up to
 four (4) years, a fine of not more than \$30,000.00 or both.

 Signature (Person who signs Application for Registration)

State of _____

County of _____

Subscribed to and sworn before me this _____ day of
 _____, 19____.

 Notary Public

¹ 21 CFR, Section 1301.17(a)

Appendix R

Guidelines for Emergency Kits in Long Term Care Facilities¹

The placement of emergency kits containing controlled substances in Long Term Care Facilities (LTCF) not registered with DEA will be deemed in compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970, **if the appropriate state agency or regulatory authority specifically approves such placement, and sets forth procedures that require the following:**

1. **Source of Supply:** The LTCF must obtain controlled substances for the emergency kits from a DEA-registered hospital/clinic, pharmacy or practitioner.
2. **Security Safeguards:** Access to each emergency kit in the LTCF must be restricted and the type and quantity of controlled substances which may be placed in the emergency kit must be specifically limited.
3. **Proper Control, Accountability and Recordkeeping:** The LTCF and the providing DEA-registered hospital/clinic, pharmacy, or practitioner must maintain complete and accurate records of the controlled substances placed in the emergency kit including the disposition of these controlled substances and take periodic physical inventories of the drugs.
4. **Administration of Controlled Substances:** In emergency medical situations when medication is needed from the emergency kit, only LTCF personnel who are authorized by an individual practitioner can administer the controlled substances. (21 CFR 1306.11 and 21 CFR 2306.21)
5. **Prohibited Activities:** Prohibited activities can result in the state revocation, denial, or suspension of having emergency kits containing controlled substances in a LTCF.

¹ Source: DEA Office of Diversion Control

Appendix S

CFR¹ Definitions

Administer

The direct application of a controlled substance to the body of a patient or research subject by 1) a practitioner (or in his presence) by his authorized agent, or 2) the patient or research subject at the direction and in the presence of the practitioner, whether such application is by injection, ingestion or any other means.

Chemicals

(see definitions for List I Chemicals, List II Chemicals, and Retail Distributor)

Dispense

Means to deliver a controlled substance to an ultimate user (patient) or research subject by, or pursuant to the lawful order of a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery. (Under the provisions of the CSA, the definition of "dispense" also includes the administering of a controlled substance.)

Dispenser

Means an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance.

Individual Practitioner

A physician, dentist, veterinarian or other individual licensed, registered or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to

¹ From the Code of Federal Regulations, the primary source for the Pharmacist's Manual.

dispense a controlled substance in the course of his professional practice, but does not include a pharmacy.

Institutional Practitioner

Means a hospital or other person (other than an individual) licensed, registered or otherwise permitted by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

Inventory

Means all factory and branch stocks in finished form of a basic class of controlled substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant under separate registration as a manufacturer, exporter, importer or distributor.

List I Chemical

The term List I chemical means a chemical specifically designated by the (DEA) Administrator in CFR section 1310.02(a)...that in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the (Controlled Substances) Act and is important to the manufacture of a controlled substance.

(Note: These chemicals are generally essential (and often precursors) for the manufacture of a specific controlled substance and actually become part of the final drug molecule. Examples include anthranilic acid, ephedrine, ergotamine, norpseudoephedrine, phenylacetic acid, phenylpropanolamine and pseudoephedrine.)

List II Chemical

The term List II chemical means a chemical, other than a List I chemical, specifically designated by the (DEA) Administrator in (CFR section) 1310.02(b)...that in addition

to legitimate uses, is used in manufacturing a controlled substance in violation of the (Controlled Substances) Act.

(Note: These chemicals are solvents and reagents that can be used in the manufacture of controlled substances. Examples include acetic anhydride, ethyl ether, potassium permanganate, acetone and toluene.)

Long Term Care Facility

A nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

Mid-level Practitioner (MLP)

An individual practitioner, other than a physician, dentist, veterinarian or podiatrist, who is licensed, registered or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of mid-level practitioners (MLP) include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists and physician assistants who are authorized to dispense controlled substances by the state in which they practice. (Other MLP disciplines recognized by DEA as controlled substance registrants include: optometrists, ambulance services, animal shelters, euthanasia technicians, nursing homes, homeopathic physicians and registered pharmacists. Because this authority varies greatly by state, check with your state licensing authority to determine which MLP disciplines are authorized to use controlled substances in a particular state.)

Pharmacist

Any pharmacist licensed by a state to dispense controlled substances and shall include any other person (e.g., pharmacist intern) authorized by the state to dispense controlled substances under the supervision of a pharmacist licensed by the state.

This refers to a chemical retail distributor which is defined as a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to legal drug products containing listed chemicals are limited almost exclusively to sales for personal use, both in number and volume of sales, either to walk-in customers or in face-to-face transactions by direct sales. (Personal use is defined as sub-threshold sales in a single transaction to an individual for legitimate medical use.)

[illegible]

Appendix U

Internet Resources:

DEA Internet Homepage:

www.DEA.gov

DEA's Diversion Control Program Website:

www.DEAdiversion.usdoj.gov

Programs

The Office of Diversion Control page is found under Programs, and includes information on:

Drug Registration

Field diversion office locations and phone numbers, offices with field registration technicians

Chemical Registration

Provisions of the Methamphetamine Control Act of 1996 and FAQ [frequently asked questions] about the Act

ARCOS (Automation of Reports and Consolidated Orders System) Reporting requirements for manufacturers and distributors of controlled substances

Publications

DEA publications of interest to the pharmacist can be found under Publications, including the updated Pharmacist's Manual (as well as the DEA manuals for physicians, mid-level practitioners and chemical handlers). Drugs of Abuse, which includes information on drug identification as well as the psychological effects of controlled substances, is also found in this section.

Additional Internet Resources

U.S. Government Printing Office:

<http://www.access.gpo.gov/nara/cfr/index.html>

Provides access to the Code of Federal Regulations (21 CFR, Parts 1300 to end), primary source for the Pharmacist's Manual, and the Federal Register which contains proposed and finalized amendments to the CFR.

Office of National Drug Control Policy (ONDCP):

<http://www.whitehousedrugpolicy.gov>

Food and Drug Administration: <http://www.FDA.gov>

FDA Matrix Page:

<http://www.medmarket.com/tenants/rainfo/fda.htm>

National Clearinghouse for Alcohol and Drug Information:

<http://www.health.org>

Internet Source for Health Care Information:

<http://www.druginfonet.com>

(Inside Back Cover)

For Additional Assistance

This publication is intended to provide guidance and information on the requirements of the Controlled Substances Act and its implementing regulations. If you require additional clarification or assistance, or wish to comment on any matter regarding DEA's requirements or regulatory activities, please contact your local DEA Diversion Field Office. Every effort will be made to respond promptly to your inquiry.

Small Business and Agriculture Regulatory Enforcement Ombudsman

Furthermore, please be aware that the Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about Federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on DEA enforcement actions, call 1-888-REG-FAIR (1-888-734-3247).

Plain Language

The Drug Enforcement Administration makes every effort to write this manual in clear, plain language. If you have suggestions as to how to improve the clarity of this manual, call or write to:

Drug Enforcement Administration
Office of Diversion Control
Liaison and Policy Section
Washington, D.C. 20537
Telephone: (202) 307-7297